EXHIBIT A

FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY, PENNSYLVANIA
CIVIL TRIAL DIVISION

GLENDA JOHNSON and STEVEN LUCIER,	)	
PLAINTIFFS	)	
	)	
	)	
v.	)	**TERM: AUGUST 2011**
	)	
SMITHKLINE BEECHAM CORPORATION	)	**CASE NO.:**
d/b/a GLAXOSMITHKLINE;	)	
GLAXOSMITHCLINE, LLC;	)	
GLAXOSMITHCLINE HOLDINGS, INC.;	)	
SANOFI-AVENTIS, U.S., LLC;	)	
AVANTOR PERFORMANCE MATERIALS;	)	
GRÜNENTHAL GMBH; and	)	
GRÜNENTHAL U.S.A.,	)	
DEFENDANTS.	)	

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER. IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED OR NO FEE.

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Philadelphia, PA 19107
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ADVISO

Le han demandado a used en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decider a favor del demandante y require que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATEMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA A LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABAGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICOS LEGALES A PERSONAS ELEGIBLES EN UN UHONORARIO REDUCIDO NINGUN HONORARIO.

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INTRODUCTION

Plaintiffs in this case suffer from severe birth defects caused by thalidomide, a drug given to their mothers in early pregnancy as a treatment for morning sickness.

Today, for the first time, evidence gathered from around the world—newly-released information, recently-accessible foreign documents, previously unseen internal corporate materials, and previously undiscovered and unavailable government documents—makes it clear that these people have not only been the victims of a medical tragedy, they have been duped by a cover-up that stretches back 60 years.

The story of the thalidomide tragedy has achieved virtually mythic status in the United States. According to that myth, thalidomide was the popular and completely innocuous European sleeping pill that was so safe that it couldn't kill animals in the laboratory and couldn't be used to commit suicide. It was sold over-the-counter in Germany, but in the United States, we were told, the drug was only available on a limited "clinical trial" basis. Americans were also told that the birth defects that occurred—virtually all in Europe– were the heartbreaking but unforeseeable ending to that story, an ending that couldn't happen here because of the limited "clinical trial" distribution.

Defendants, who are the companies responsible for developing, designing, manufacturing, and distributing the drug (or their successors), were portrayed in the media as responsible pharmaceutical businesses that had conducted all of the required tests and taken all of the proper precautions before marketing the drug.

Newly-accessible evidence reveals, however, that this story–aggressively promoted by these Defendants and widely accepted--was not the truth. Instead, it was a carefully constructed lie sold to the public to protect these companies from having to accept responsibility for what they had done.

And what they had done was nothing short of creating every mother's nightmare.

The families who suffered because of the Defendants' actions never knew that the story of how thalidomide was distributed in the U.S.—only as part of scientific clinical trials in which records are kept and results were monitored, was just that—a story.

The truth is that Richardson-Merrell launched a massive *marketing* effort-- not a research effort--eventually distributing at least 2.5 million doses of thalidomide in the U.S. That marketing effort targeted those most vulnerable to their destructive drug-- hospital OB-GYN departments and pregnant women.

None of the mothers-to-be who innocently took thalidomide, under doctor's orders, knew that they were taking a drug deadly to adult laboratory animals.

None of these mothers knew that they were taking a drug that had never been tested on a single pregnant animal before being given to unsuspecting pregnant women in 46 countries, including this one.

And none of them knew they were taking a drug that Grünenthal had learned would cause birth defects in *humans* by 1956, something Smith, Kline & French learned by 1958.

Nor did these unsuspecting women know that the drug they were taking had been designed, manufactured, and promoted by a German company–Defendant Grünenthal-- that actively recruited Nazi war criminals to make the decisions about how its drugs should be marketed, and what warnings would be provided.

One of these men, Dr. Heinrich Mückter, had been charged by the Polish government for his participation in the typhus experiments conducted at the Krakow camps. It was Dr. Mückter–a man who surely had a history of making cruel and calloused medical decisions–who was given primary decision-making authority over the marketing of thalidomide.

Instead of revealing that thalidomide could cause birth defects so that warnings could be given and thousands of families spared a lifetime of heartache, these companies concealed the truth and marketed thalidomide as "safe" and "harmless," particularly for pregnant women. Smith Kline & French went so far as to lie to Congress about it.

In the decades that have passed, they have continued to cover up the tragic truth about what they knew and what they did-- denying justice to their many victims.

THE PARTIES

1. Plaintiff Glenda Johnson, who suffers from serious and permanent thalidomide-related injuries, is an individual residing in the state of Louisiana.

2. Steven Lucier, who suffers from serious and permanent thalidomide-related injuries, is an individual residing in the state of Pennsylvania.

3. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a successor to Smith Kline and French [hereinafter "SKF"]. SKF is a Pennsylvania corporation

with a principal place of business in Philadelphia County, Pennsylvania, a status it has held since 1929, its date of original incorporation in this county (as the Smith Kline & French Corporation). Even prior to its date of incorporation, however, and since the early 1800s, SKF or its predecessors have been continuously engaged in the business of selling pharmaceutical products and prescription drugs in this state, and have always maintained their principal place of business in Philadelphia County. To that end, SKF and its predecessors have engaged in research–including clinical trials and testing–product development, testing, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. On October 27, 2009, SKF filed articles of dissolution with the Pennsylvania Secretary of State's office. Pursuant to 15 Pa. C.S. § 1979, SKF continues to be is a citizen of Pennsylvania.

4. Defendant GlaxoSmithKline LLC [hereinafter "GSK LLC"] is currently a Delaware limited liability corporation. GSK LLC has admitted to having a principal place of business in Pennsylvania. Since 2009, GSK LLC has been engaged in the research–including clinical trials and testing–product development, testing, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. GSK LLC alleges that it succeeds to the liabilities of SmithKline Beecham Corporation.

5. Defendant GlaxoSmithKline Holdings, Inc. [hereinafter "GSK Holdings"] is a Delaware corporation with a principal place of business in Philadelphia County, Pennsylvania. GSK Holdings is a holding company and a member of GSK LLC. Upon information and belief,

GSK Holdings is a sham corporation formed to create diversity in Pennsylvania-filed cases and prevent the state courts of Pennsylvania from exercising jurisdiction over the Philadelphia-based pharmaceutical business and activities of SmithKline Beecham/GSK LLC.

6. Defendant Sanofi-Aventis, U.S., LLC ["Sanofi"] is a Delaware corporation with a principal place of business in Bridgewater, New Jersey. Sanofi is the legal successor to the liabilities of the William S. Merrell Company, National Drug Company, and Richardson-Merrell, Inc., the North American licensee/distributors of thalidomide. Sanofi and its predecessors are/were pharmaceutical companies engaged in research–including clinical trials and testing–product development, testing, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. At all times relevant hereto, the William S. Merrell Company, National Drug Company and Richardson Merrell, Inc. distributed the confirmed teratogenic drug, thalidomide, throughout the United States and Canada, and in this state, causing Plaintiffs to sustain serious birth defects.

7. Defendant Avantor Performance Materials is a New Jersey corporation. As of April, 2011, Avantor's headquarters and principal place of business have been located in Center Valley, Pennsylvania. Avantor is, upon information and belief, the legal successor to the J.T. Baker Company, which has been involved in the business of manufacturing pharmaceutical products in New Jersey since 1904. At all times relevant hereto, J.T. Baker was a subsidiary of Richardson-Merrell, Inc. and, upon information and belief, it manufactured the teratogenic drug,

thalidomide in the state of New Jersey, distributing the drug throughout the United States, Canada, and in this state, causing Plaintiffs to sustain serious birth defects.

8. Grünenthal GmbH is a corporation duly incorporated pursuant to the laws of the Federal Republic of Germany, with a principal office in Aachen, Germany. Since 1946, Grünenthal has been engaged in the business of manufacturing, selling and distributing pharmaceutical products worldwide, including to the United States. At all times relevant hereto, Grünenthal designed, developed, patented, manufactured, distributed, marketed, and directed its teratogenic drug, thalidomide, worldwide, including in the United States and this state. Grünenthal continues to distribute its drugs throughout the United States and in this state through licensing partners, including Johnson & Johnson, Ortho-McNeil, and Endo Pharmaceuticals As such, Grünenthal is subject to suit in the courts of this state.

9. Grünenthal U.S.A. is a Delaware corporation with a principal place of business in Bedminster, New Jersey. It is the U.S. subsidiary of Grünenthal GmbH. Upon information and belief, Grünenthal U.S.A. is the alter ego of Grünenthal GmbH.

JURISDICTION AND VENUE

10. At relevant times, SKF tested thalidomide in this district, distributed thalidomide to doctors and patients without a warning in and from this district, designed and implemented a non-consensual thalidomide clinical trial from this district, and made material omissions and misrepresentations in this District. SKF has also engaged in continuous and systematic business activities in this district over a period of more than 100 years. This Court may exercise *in*

personam jurisdiction over SKF consistent with the Due Process clause of the Fifth and Fourteenth Amendments, and under 42 Pa. C.S.A. 5301(a)(2)(iii) and/or 42 Pa.C.S.A. 5322.

11. Jurisdiction is proper against GSK LLC as the admitted successor to SKF, which tested thalidomide in this district, distributed thalidomide to doctors and patients without a warning in and from this district, designed and implemented a non-consensual thalidomide clinical trial from this district, and made material omissions and misrepresentations in this District. GSK LLC also owns and operates an established pharmaceutical business in this district, and has continuous and systematic contacts in this district. This Court may exercise *in personam* jurisdiction over GSK LLC consistent with the Due Process clause of the Fifth and Fourteenth Amendments, and under 42 Pa. C.S.A. 5301(a)(2)(iii) and/or 42 Pa.C.S.A. 5322.

12. Jurisdiction is proper against GSK Holdings as the sole member of GSK LLC. Its principal place of business as sole member of GSK LLC, which owns and operates an active pharmaceutical business in this District, is in Philadelphia, Pennsylvania, and it has continuous and systematic contacts in this District. This Court may exercise *in personam* jurisdiction over GSK Holdings consistent with the Due Process clause of the Fifth and Fourteenth Amendments, and under 42 Pa. C.S.A. 5301(a)(2)(iii) and/or 42 Pa.C.S.A. 5322.

13. Jurisdiction is proper against Sanofi-Aventis as the successor to Richardson-Merrell and its subsidiaries/divisions, the William S. Merrell Company and National Drug Company. At all relevant times, Richardson-Merrell, the William S. Merrell Company and National Drug Company tested thalidomide in this district, distributed thalidomide to doctors and patients without a warning in and from this district, designed and implemented a non-consensual

thalidomide clinical trial from this district, and made material omissions and misrepresentations in this District. As one of the nation's largest pharmaceutical/diversified health care companies, Sanofi-Aventis directs pharmaceutical products (including but not limited to Ambien and Plavix) to this state, and this district on a regular and sustained basis, it conducts research and development operations in this state, it maintains a research facility in this state that employs 350 people in Malvern, Pennsylvania, and 200 field employees, and it receives substantial financial benefits and profits from its business activities in this state. This Court may exercise *in personam* jurisdiction over Sanofi-Aventis consistent with the Due Process clause of the Fifth and Fourteenth Amendments, and under 42 Pa. C.S.A. 5301(a)(2)(iii) and/or 42 Pa.C.S.A. 5322.

14. Jurisdiction is proper against Avantor Performance Materials as the successor to J.T. Baker Company, a subsidiary of Richardson-Merrell. At relevant times, J.T. Baker Company manufactured thalidomide and distributed it for use in this district, distributed thalidomide to doctors and patients without a warning in and from this district, and made material omissions and misrepresentations in this District. Moreover, as of April 2011, Avantor's corporate headquarters have been located in Center Valley, Pennsylvania. Avantor's business activities in this state are continuous and systematic, and this Court may exercise *in personam* jurisdiction over Avantor consistent with the Due Process clause of the Fifth and Fourteenth Amendments, and under 42 Pa. C.S.A. 5301(a)(2)(iii) and/or 42 Pa.C.S.A. 5322.

15. Jurisdiction is proper against Grünenthal GmbH because at all relevant times, Grünenthal manufactured thalidomide and purposefully availed itself of the markets in the United States and this state by intentionally introducing thalidomide into the stream of commerce

in the United States and this state. Grünenthal's practice was to ship thalidomide directly to the United States, for eventual distribution by licensee, Richardson-Merrell/the William S. Merrell Company and, upon information and belief, Richardson-Merrell' subsidiary, the Pennsylvania corporation, National Drug Company. Because Grünenthal shipped its drug directly to the United States, Grünenthal knew and intended that its thalidomide products would be sold and distributed from and within the United States and this state. Grünenthal obtained U.S. trademark protection for its thalidomide drug product Softenon in 1960, and for its company name in 1953. Grünenthal also directed its thalidomide drug products into the United States and this state by providing them directly to Philadelphia-based SKF for use in clinical trials and animal tests. Grünenthal held the U.S. patent for thalidomide and Grünenthal controlled the manner in which its thalidomide drug products were marketed and distributed in the United States and this state, and was jointly responsible for the content of any health and safety warnings. Upon information and belief, Grünenthal's licensing agreement with Merrell entitled it to receive on an ongoing basis between 3 and 10% of net North American sales. In addition, Grünenthal has continuously and systematically availed itself of U.S. markets, and of the markets of this state with respect to its sale and marketing of other drug products in this state to the present day. It has continued to manufacture drug products, including but not limited to tramadol, tapentadol/oxymorphone, and axomadol, and to systematically and continuously ship those products to the United States and into commercial markets in the United States and this state, acting through joint ventures and licensing agreements. One of Grünenthal's partnership arrangements was specifically entered into so that Grünenthal could "take part in events on the US market on short notice." Its studies

are relied upon by FDA in its consideration of New Drug Applications submitted for these drugs, and as such, has been subject to FDA's Foreign Labs Inspection program. It obtains and holds U.S. patents for drug products; in 2009, almost half the patents awarded to the company were U.S. patents. And as it did with thalidomide and as is its practice, Grünenthal shares responsibilities for product development and commercialization activities with its licensees, activities that affect how these drugs are marketed and sold in the United States and this state. Grünenthal has continuously received significant and financial benefits from these activities, revenues based on annual total net sales of such drugs. Grünenthal also conducts pharmaceutical drug clinical trials in the United States and this state through its subsidiary, Grünenthal USA, Inc., which is, upon information and belief, the alter ego of Grünenthal GmbH.

16. Jurisdiction is proper over Grünenthal USA, Inc. because Grünenthal USA, Inc. is a sham corporation, and is the alter ego of Grünenthal, so the parent's contacts with the forum are properly imputed to the subsidiary. Upon information and belief, Grünenthal USA is a mere extension of its parent, Grünenthal, and would not be financially stable or viable on its own. Upon information and belief, the owner of Grünenthal USA, Inc. is the Wirtz family, including but not limited to Sebastian Wirtz; the Wirtz family also owns and controls the parent company, Grünenthal. According to court documents submitted by Grünenthal USA, Mr. Wirtz is and has been a principal of Grünenthal USA, Inc. The companies share at least one board member, Dr. Eric-Paul Paques. As Grünenthal USA has alleged in court proceedings, its business is to provide operational and regulatory support for the clinical trials conducted for drugs developed by its parent; of necessity, then, the parent Grünenthal directs and controls the support activities

undertaken by Grünenthal USA, Inc. Grünenthal USA, Inc. has no independent public internet presence; instead, contacts with the company are directed to Grünenthal. Grünenthal's privacy policies are applied to Grünenthal USA online contacts. Grünenthal USA is merely a liability shield created by Grünenthal in hopes of conducting clinical trials on U.S. citizens without accountability for those activities. Jurisdiction is also proper based on Grünenthal USA's own activities. Grünenthal USA has continuous and systematic contacts with this state because, upon information and belief, it regularly conducts clinical trials for drug products in this state, and has obtained Pennsylvania state funding for such trials. Grünenthal USA also holds the trademark rights for a variety of drug products directed into the stream of commerce in this state and the United States, including Abiantem, Guard, HM-Guard, Morphiguard, and Ixibaren.

17. Venue is proper because SKF's principal place of business is in Philadelphia, Pennsylvania and Avantor's headquarters is located in Center Valley, Pennsylvania. In addition, SKF has conducted its pharmaceutical business activities in the Commonwealth of Pennsylvania and in Philadelphia for more than 100 years. At relevant times, SKF tested thalidomide in this district, distributed thalidomide to doctors and patients without a warning in and from this district, designed and implemented a non-consensual thalidomide clinical trial from this district, and made material omissions and misrepresentations in this District so as to subject it to *in personam* jurisdiction in this District. Venue is proper in this district as against all Defendants pursuant to Pa. R. C. P. No. 2179 and 1006(c).

STATEMENT OF FACTS

18. Administering thalidomide to pregnant women has been called the biggest mistake made in modern medicine. First sold in Germany as an over-the-counter remedy for everything from the flu to insomnia to morning sickness, the drug was advertised as "completely harmless" and "atoxic" during the nine years that it was distributed for human use. Far from being harmless, it was learned in late 1961 that the ingestion of even one pill during the early stages of pregnancy caused severe birth defects, including malformed limbs, curved spines, malformed or missing internal organs, and damaged ears, eyes, and gastrointestinal systems.

19. The companies responsible for the design, manufacture, promotion, distribution and marketing of thalidomide–Defendants here–explained that the birth defects were completely unforeseeable. They all insisted they had fully and adequately tested the drug, that they had no indication thalidomide was dangerous, and that there was simply "no way" they could have foreseen the danger.

20. They also minimized the extent of the drug's distribution here and denied having recommended that the drug be used during pregnancy. They concealed the role that the German company, Grünenthal, played in the marketing, promotion and distribution of the drug in North America.

21. That effort was successful. Senator Hubert Humphrey told the public that Richardson-Merrell had acted responsibly throughout and complied with every regulation." Next to no mention was made of the German company. The thalidomide tragedy was portrayed as a European problem, one that American families had been spared due to the diligence of an FDA analyst, Dr. Frances Kelsey, who refused to approve the commercial sale of the drug in this

country. Of the 17 malformed babies supposedly born in America, about half were said to have been caused by thalidomide obtained overseas.

22. In those days when the public's ability to learn about current news events was confined almost exclusively to what could be gleaned from the daily paper or the evening news, it was beyond most people's abilities to gain additional facts. These companies did not disclose the facts, but have concealed them to the present day. In the case of thalidomide, there were significant legal impediments that barred public and media access to relevant documents for decades; indeed, at least one injunction barring disclosure of highly relevant evidence remains in place today. Language barriers also hampered the North American public's ability to access the facts. There was no Internet, or digitally searchable documents. There was no Freedom of Information Act providing the public with access to government documents.

23. But documents only recently unearthed, or only recently accessible and available in English, reveal that the representations made by these companies as the tragedy unfolded were false.

24. Each Defendant here participated in the effort to hide the facts relating to its distribution and marketing of thalidomide in this country. Smith Kline & French ["SKF"], the predecessor to the Smith Kline & Beecham Company and the Glaxo defendants, concealed for more than 50 years the fact that it had conducted a clinical trial involving at least 875 patients ationwide in 1956 and 1957. Its President lied to Congress about the fact that at least one, if not two malformed babies were born to women participating in this trial. Though Grünenthal knew for certain that SKF had conducted these experiments and Merrell should have known it, both

companies cooperated in the concealment of SKF's early use of the drug with pregnant women in the U.S..

25. After the tragedy in Europe came to light, Merrell's medical research director, Dr. Carl Bunde, gave public statements and Congressional testimony assuring the public that thalidomide was never sold in the U.S. so the birth defect problem seen in Europe would not be a problem here. Not only did Merrell not sell the drug, assured Bunde, but Merrell never recommended to its "clinical trial" investigators that the drug be tested for the treatment of morning sickness in early pregnancy. Instead, as Bunde told the public in *Life* magazine, Merrell's "investigators" were told to focus on older patients, hospitalized patients, orthopedic patients and psychiatric patients. And when the "heartbreaking tragedy of the malformed babies in Europe, reportedly related to...thalidomide" became public, Bunde assured Congress and the public that Merrell engaged in an "extraordinary program" and a "massive effort" to reach all clinical investigators and tell them to return or destroy the drug. Relying on Bunde's July 28, 1962 statement and his testimony before Congress, FDA Commissioner George Larrick told the public a few days later that to date, the U.S. had seen "no deformed infants...whose deformity was associated with the thalidomide testing program in the U.S."

26. Although Grünenthal had not only developed, manufactured and licensed thalidomide, but had directed the marketing efforts in licensee countries like this one, it disappeared from the public's view in the aftermath of the tragedy. The company provided virtually no public information about its involvement in the North American thalidomide distribution effort. However, when interviewed by FDA's Glenn Slocum in October 1962,

Grünenthal's Dr. von Schrader Beielstein specifically confirmed as accurate Merrell's description of events.

27. SKF and Merrell concealed their contractual relationship with Grünenthal, though the company had manufactured thalidomide for direct shipment to the U.S. and Canada, and had controlled the marketing campaign used to promote thalidomide.

28. SKF did not disclose that it had experimented on pregnant women with Grünenthal-supplied thalidomide, save in a single unreported letter to Congress on August 27, 1962, so there was no publicly-available information linking SKF to Grünenthal and thalidomide.

29. Merrell rarely acknowledged its relationship with Grünenthal. Remarks Bunde made in a highly-publicized July 28, 1962 press statement made no mention whatsoever of Grünenthal. His August 10, 1962 article in *Life* magazine never named Grünenthal, but stated only that thalidomide had been "prepared" in 1953 by a "recognized and respected West German chemical concern." When describing to Congress how Merrell learned of the birth defect hazard in November 1961, the summary of Bunde's testimony explained that Merrell simply "received a cable from Germany." Nor did the packaging and labeling information identify Grünenthal. Upon information and belief, Grünenthal directed Merrell to downplay any relationship between the companies, and these companies agreed to do so..

30. The companies took numerous steps to convince the public that no wrongful conduct had occurred. In his *Life* magazine article, Dr. Bunde explained that Merrell "followed the normal course of all responsible American pharmaceutical manufacturers" in its testing of

thalidomide. He told the public that Merrell "had not heard a whisper of suspicion from anywhere in the world that [thalidomide] could affect the unborn" until November 1961, when the news from Europe became public.

31. Bunde also told Congress that thalidomide had been subjected to "rigorous" testing with both humans and animals, testing that had revealed no serious toxicity of any type. He specifically testified that Merrell had administered thalidomide to pregnant rats. Falsely insinuating that this testing had occurred prior to the distribution of thalidomide, he stated that of the more than 1500 offspring delivered by June 1, 1962, none had displayed evidence of malformation. Relying on Merrell's public statements and statements to Congress, U.S. Senator Hubert Humphrey told the Associated Press in publicized comments that Merrell had "acted responsibly throughout and complied with every regulation."

32. Grünenthal has always taken the public position that during development, thalidomide was "subjected to the usual battery of investigations," tests that were " in line with the pharmacological and toxicological investigations carried out in rodents." The company states on its website to the present day that testing for teratogenic effects was in no way indicated, and that the German court presiding over the trial of its executives had expressly found that its testing had been "adequate." The company maintained that the tests that it did conduct "revealed no signs of risk whatsoever." Until about February 2011, Grünenthal's website stated that researchers were unable to produce malformations in laboratory animal tests until 1964, almost three years after the human birth defect hazard was publicized in Europe, suggesting that the technology was simply unavailable any earlier. Former Grünenthal CEO

Sebastian Wirtz told the *Financial Times* in 2007 that "there was no way the tragedy could have been averted."

33. SKF took up that message itself in August 1962. Though never admitting to the public that it even performed thalidomide experiments on pregnant women, SKF President Walter A. Munns, issued a press release on August 23, 1962 stating that thalidomide "had been thoroughly tested" but that there were "no known tests in animals which could have predicted those abnormal births in human beings." SKF repeated Senator Humphrey's statement that Merrell had complied with every regulation.

34. Grünenthal, Merrell and SKF's joint campaign made three points: 1) that thalidomide had not caused birth defects in this country, 2) that the German company responsible for the thousands of malformed German babies had not been involved with the North American use and distribution of thalidomide; and 3) that the companies had not acted wrongfully, but had done all that was scientifically possible at the time to discover the potential for harm.

35. The myth promoted by these companies has persisted because much of the relevant evidence was inaccessible to the public. A grand jury investigation of Merrell sequestered documents and witnesses until the attention of the media had turned to other issues. Grünenthal destroyed its animal testing data in 1959. Merrell refused to let its employees give statements to German prosecutors investigating the thalidomide tragedy. There was no Freedom of Information Act and there was no Internet to provide victims with access to government documents.

36. Other sources of evidence that would have contradicted the company-promoted party line were beyond the reach of ordinary citizens by virtue the barriers of either law or language. The evidence generated during the German prosecution of eleven Grünenthal executives was largely in German, and was itself insulated from public access for a period of 10-30 years. When the legal prohibition on public access expired, there was no longer any reason to write about the decades-old tragedy, or to translate those documents.

37. Similarly, English-language evidence produced in litigation brought by UK thalidomiders in the 1960s and 1970s was insulated from public disclosure by laws that prevented the publication of newspaper articles about the facts learned in that decade-long litigation. Those laws did not bind Merrell, SKF, or Grünenthal, who could continue to present their own self-serving version of what was known, and by when. And even after the UK litigation ended, the documents containing many hitherto unknown facts were insulated from disclosure by an injunction which remains in force to this day.

38. However, in recent months, Plaintiffs' counsel has gained access to evidence revealing that the public story told by Grünenthal, by SKF, and by Merrell was just that—a story.

Smith Kline & French's 50-year secret: By 1958, at least two of its study subjects had given birth to malformed babies

> Boy 8/28/58–Full term infant with bilateral phocomelia of upper extremities. This case appears to involve S.K.F. thalidomide (Philadelphia District Report of 8/13/62.)
>
> –FDA Summary of Abnormal Infants Associated with Thalidomide

> Dr. Nance, Medical Director of S.K. & F. ....told me that he was contacting the physician who reported the case of a malformation associated with S.K.F.'s ....Thalidomide which was reported .....by Mr. Munns' letter of 7/31/62.
>
> –George Gerstenberg, FDA Inspector
> "Thalidomide Investigation, Report of Malformation"
> August 13, 1962

> "Our clinical testing involved approximately 875 patients...No effect which might be characterized as phocomelia or akin thereto was observed."
>
> –SKF President Walter A. Munns
> Letter to Senator Hubert Humphrey
> August 27, 1962

39. Grünenthal maintains that it synthesized thalidomide in 1953, and that it began human clinical trials in Europe in 1954-1955.

40. By 1955 or early 1956, Grünenthal and SKF began discussing a licensing agreement in which Grünenthal would grant SKF the right to market thalidomide in the U.S. and, upon information and belief, in Canada.

41. Before finalizing any licensing arrangement, it was SKF's practice to conduct its own investigation and testing. It was also SKF's practice to enter into a Preliminary Licensing Agreement. The agreement that SKF used with other drugs mandated the "free and prompt" disclosure of findings relating to the drug under evaluation; upon information and belief, SKF executed a substantially similar agreement with Grünenthal.

42. Grünenthal used a similar agreement to formalize licensing and investigative agreements. In addition to mandating information-sharing, it also prohibited Grünenthal's licensing from disclosing scientific studies or making other disclosures that might be harmful to

Grünenthal's business interests, at least after the agreement terminated. Upon information and belief, SKF and Grünenthal executed such an agreement.

43. SKF has never revealed its relationship with Grünenthal and to date, SKF's involvement with thalidomide is virtually unknown. If SKF is mentioned in media reports about the thalidomide tragedy at all, it is with respect to animal studies it conducted in 1955 and 1956. According to SKF, those studies convinced it that thalidomide had no significant pharmacological activity or therapeutic benefit, so it decided not to market the drug.

44. Plaintiffs' counsel has recently obtained access to what is believed to be the only remotely public disclosure of those SKF animal tests: an August 27, 1962 letter written by SKF President Munns to Senator Hubert Humphrey, who was at that time Chairman of the Senate Subcommittee on Reorganization and the International Organizations of the Committee on Government Operations. In that letter, President Walter Munns told Congress in August 1962 that SKF conducted experiments on 700 animals of five different species (rats, mice, dogs, guinea pigs and monkeys), testing which concluded in October 1956. Upon information and belief, this disclosure was never reported in the American media.

45. Though he disclosed that SKF conducted animal tests on thalidomide six years earlier, Munns denied that SKF had tested any pregnant animals. SKF's failure to conduct such tests represented a departure from its prior practice. Had it administered thalidomide to pregnant animals from its test species—rats, mice, dogs, guinea pigs and monkeys-- it would have learned that thalidomide could harm a developing fetus.

46. Upon information and belief, Munns misrepresented the facts, and concealed the fact that SKF had conducted tests on pregnant animals in 1955 and 1956. If SKF conducted such tests, it would have been obligated to report those findings to Grünenthal at least.

47. Munns' August 27, 1962 letter is also, upon information and belief, the only public admission by SKF that it conducted human clinical trials. These began no later than November 1956. These trials have never been disclosed elsewhere, and, upon information and belief, they were never covered in the American media. Because SKF had not tested thalidomide on pregnant animals, it was a significant breach of medical research ethics to test the drug on pregnant women.

48. SKF provided no hazard warning to its clinical trial participants, including but not limited to pregnant women, or to its clinical trial investigators/physicians. Nor did it obtain these study subjects' informed consent to participate in such an experiment.

49. By 1956, SKF knew or should have known of several facts that ought to have raised the concern that thalidomide might cause birth defects, prompting the company to both warn and investigate. It should have known that thalidomide posed a birth defect risk because its low molecular weight allowed it to cross the placenta. It should have known that thalidomide posed a birth defect risk because it was in the same chemical family as the known teratogen, aminopterin. It also caused side effects known to increase the risk of birth defects or pose a threat to the developing fetus, including neurological damage and thyroid depression.

50. Munns' August 27, 1962 letter is a response to questions put to him by Senator Humphrey. Specifically, Senator Humphrey specifically asked Munns not only whether SKF

had conducted clinical trials, but whether it had noted any side effects in either its animal or its human experiments. Senator Humphrey asked specifically about "effects which might be characterized as phocomelia, or akin thereto."

51. Mr. Munns assured the Senator that "No effect which might be characterized as phocomelia or akin thereto was observed" amongst SKF's study subjects. Phocomelia ["seal limbs"] is the rare congenital limb malformation that was the most recognizable of the birth defects caused by thalidomide.

52. Munns' letter was a news non-event, given his assurances that no harmful side effects had been detected. It was also a lie.

53. In recent weeks, Plaintiffs' counsel has located a memorandum written by FDA inspector George Gerstenberg on August 13, 1962; the document was housed in a federal archive created decades later. That memo reveals that on July 31, 1962–less than a month before his letter to Humphrey--Munns revealed to FDA Commissioner Larrick that at least one malformed baby had been born to one of its thalidomide clinical trial patients in August, 1958. Upon information and belief, FDA record repositories contain a memorandum written by Dr. Frances Kelsey on September 5, 1962, which indicates that not one, but two malformed babies were born to women participating in the SKF.

54. The Gerstenberg memo indicates that on or about August 13, 1962, SKF's Medical Director Maurice Nance asked that company's after-the-fact disclosure be kept "anonymous."

55. These acts of concealment were part of a pattern for SKF, which instructed its salesmen–its detail men–to "Mention only advantages and remain quiet about disadvantages" when promoting the company's drugs to doctors.

56. In his August 27, 1962 letter to Senator Humphrey, Munns states that SKF's clinical trial concluded in December 1957 but admits that SKF took no steps to recall thalidomide from its clinical trial investigators in 1957 or thereafter. At least one investigator would admit they he was still *receiving* thalidomide for the purposes of conducting tests in *1958*.

57. For two such babies to be born to the small fraction of the SKF 875 study subjects that would have been pregnant during the SKF clinical trial would have been significant and material. SKF had both a contractual and a common law duty to report these findings to Grünenthal, at least. SKF also had a clear legal duty to report these births to Congress upon receipt of its request. Munns informed Congress that all test results had been delivered to Grünenthal.

58. Grünenthal has consistently maintained that it had no clue that thalidomide could cause birth defects until November 1961 (Even after that date, Grünenthal has vigorously disputed thalidomide's ability to cause birth defects). So SKF either concealed the birth defect hazard from Grünenthal, or it disclosed the facts to Grünenthal as its President said it did, conspiring with Grünenthal to keep the facts of the birth defect hazard out of the public domain.

59. Upon information and belief, 100% of Merrell's North American thalidomide distribution–a campaign targeting pregnant women-- occurred after SKF's pregnant study subjects gave birth to these two malformed babies. SKF's concealment of the knowledge that

thalidomide caused birth defects gave Grünenthal and Merrell the cover they needed to continue to market thalidomide as safe, to continue to target pregnant women in their promotional campaigns, and to maintain that they had no reason to know of any reproductive hazards for decades thereafter.

60. On August 23, 1962, SKF President Munns issued a public statement about thalidomide entitled "For Your Information," with an attached paper called "Thoughts on Thalidomide." Munns never reveals that SKF conducted human clinical trials in this statement, nor does he reveal that malformed babies were born to the pregnant women participating in the study. Instead, Munns tells the public that the tragedy was unavoidable because "there were no known test in animals which could have predicted the abnormal births in human beings."

61. This representation was false. Even if it were true that "animal" studies would not have revealed a risk to the fetus–which it was not–President Munns knew on the basis of SKF's human clinical trial that thalidomide could cause birth defects

62. Mr. Munns' public "Thoughts on Thalidomide" was intended to convince the public that none of the companies involved in the manufacture or distribution of thalidomide had engaged in wrongful conduct. It was also intended to hide from its own clinical trial participants the fact that SKF had conducted its own thalidomide test.

Richardson-Merrell: North American face of thalidomide and Grünenthal's partner in concealment

"In retrospect I realize now that it would have been dangerous in early pregnancy, but we weren't concerned with it at that time..."

–Dr. Raymond Pogge
Medical Director, Richardson-Merrell

63. After SKF declined to market thalidomide, Grünenthal approached Richardson-Merrell and its two subsidiaries, Cincinnati-based William S. Merrell Corporation and Philadelphia-based National Drug Company [hereinafter, jointly, as "Merrell"]. In October 1958, Grünenthal entered into a licensing agreement with Merrell granting it exclusive marketing rights in North America.

64. Upon information and belief, the licensing agreement between Grünenthal and Merrell obligated Merrell to bring the thalidomide products to market in the U.S. and Canada in a short period of time, a period of time that did not allow Merrell to conduct and complete independent animal tests before commencing its human clinical trials. Recently-discovered documents located in a German archive indicate that, upon information and belief, the Merrell-Grünenthal licensing agreement required that Merrell engage in "intensive promotion" of thalidomide, but not intensive research. Upon information and belief, the aggressive marketing schedule dictated by Grünenthal obligated Merrell to rely upon Grünenthal's own testing to a significant degree.

65. In May and June of 1962, Merrell's medical research director Dr. Carl Bunde would tell Congress and the public that thalidomide had been the subject of three years of "rigorous" testing and toxicity studies before Merrell filed an application to distribute the drug in the U.S. or Canada. Bunde also implied that Merrell itself had conducted reproductive studies on

animals before distributing thalidomide to humans, this testing never happened. Neither statement was true. As a document recently obtained from a German archive confirms, Merrell—like SKF and Grünenthal--did *no* reproductive animal testing before distributing thalidomide. As with SKF, this was a breach of medical ethics and a deviation from Merrell's established practice.

66. Merrell did conduct some tests on adult animals, however. Recently-accessible evidence located in a German archive reveals that when Merrell researchers tested thalidomide in syrup form in 1959, they found that the drug was acutely toxic at 500 mg/kg and 1000 mg/kg doses in rats and mice. Grünenthal's UK licensee, Distillers, made similar findings at about the same time. These results were concealed from the public but not drug-developer, Grünenthal.

67. Merrell researcher James Knox Smith confirms in these documents that Merrell concealed these test results so it could perpetuate the story that there was no "LD 50" for thalidomide well after the time the thalidomide tragedy came to light, LD 50 representing the dose at which ½ of a population of test animals is killed by a test drug. According to Grünenthal and Merrell the "fact" that thalidomide had no LD 50 meant that it was "safe" and "harmless," and the companies promoted the drug that way.

68. Like SKF, by 1958, Merrell also knew or should have known that thalidomide posed a risk to the developing fetus since its low molecular weight allowed it to cross the placenta and reach the fetus. Merell also knew that it was in the same chemical family as the known teratogen, aminopterin, and that thalidomide could depress thyroid function and cause

neurological damage in adults, conditions that a reasonable scientist would have considered a potential threat to a developing fetus.

69. Merrell's medical director, Dr. Raymond Pogge acknowledged in February 1959 that the company had no human safety data (because Grünenthal had not provided any). Even though it had no knowledge that the drug was safe for humans, and even though it knew that thalidomide could be lethal to lab animals and had the potential to harm the fetus, Merrell commenced a human clinical trial in February 1959. That trial was expanded to include pregnant women in all stages of pregnancy no later than May 1959. Since Merrell had not conducted an tests on pregnant animals, testing thalidomide on pregnant women was a significant breach of medical ethics.

70. Merrell's "clinical trial" included women in all stages of pregnancy from the outset. However, on March 20, 1960, recently-available evidence confirms that Merrell's Dr. Raymond Pogge specifically requested that Cincinnati-based clinical investigator, Dr. Nulsen, use the drug to treat the nausea of early pregnancy. In 1962, Merrell's Carl Bunde would deny that this ever occurred.

71. Merrell did not disclose any of thalidomide's known side effects to clinical trial participants or their doctors. Instead, it promoted the drug as safe ["no LD 50"] and harmless, appropriate for use by women during pregnancy.

72. The recently-obtained script from Merrell's internal marketing program, known as the "Kevadon Hospital Program" expressly directs Merrell salesmen ("detail men") to tell doctors that there was no LD-50 for thalidomide. According to Merrell spokesman Dr. John

Chewing , as far as Merrell was concerned in those early days, thalidomide was the "safest thing since water." In fact, Merrell's Dr. Raymond Pogge continued to represent that Merrell had been unable to kill animals in its attempt to establish an acute toxic dose for the drug until 1969 at least.

73. After distributing the drug on an "investigatory" basis for at least 19 months, Merrell subsidiaries William S. Merrell Corporation and National Drug Company filed New Drug Applications ("NDA") to market thalidomide as "Kevadon," and "Contergan" on or about September 13, 1960. Documents recently accessed in the German archive confirm that these NDAs and the marketing brochures submitted in support stated that there was no "LD 50" for thalidomide, and that the drug was safe for use during pregnancy, with no qualifications as to the stage of pregnancy.

74. Merrell's NDAs have never been made publicly available in their entirety. Recent research has unearthed a page from the *Congressional Record* which confirms that Merrell marketed thalidomide as effective for the treatment of nausea in pregnancy, a condition that occurs in the early stages of pregnancy.

75. During its "clinical trial," Merrell not only falsely represented that the drug was safe for use by pregnant women, it concealed knowledge of side effects like polyneuritis, a serious nerve condition. By the time Merrell's two subsidiaries filed those NDAs in September 1960, Grünenthal had received more than 1600 complaints of side effects, including hundreds of cases of polyneuritis. Its UK licensee, Distillers had notice of at least five polyneuritis cases months before Merrell filed its NDA. Under the terms of the licensing agreement, this

information should have been disclosed by the licensees to Grünenthal and vice versa. Merrell had access to at least some Distillers and Grünenthal research because it submitted some of their studies in support of its NDA.

76. A document accessed only last week in a German archive confirms that Merrell scientists had actual knowledge of the polyneuritis risk by 1959, well before Merrell filed its New Drug Application at the FDA and in the early stages of its "clinical trial." In 1959-1960, Merrell subsidiary, National Drug Company, employed a physician named Dr. Gustav Martin. In 1963, Dr. Martin wrote to the German consulate in Philadelphia, informing the consulate that he was concerned about thalidomide in 1959 because he had reviewed a Grünenthal document discussing that hazard. To Dr. Martin, "This seemed to me to indicate a potential for toxicity which would be very great."

77. The polyneuritis risk is significant because the adult nerve system is not easily damaged. Since the fetal liver is far less effective at processing toxins, the fetus is more vulnerable to toxic insults than adults. Since thalidomide could harm the adult nervous system and cross the placental barrier, Merrell should have known that it posed some risk to the developing fetus.

78. However, Merrell concealed the fact that thalidomide posed a polyneuritis risk.

79. No more than a month after filing the NDAs, Merrell accelerated its distribution of thalidomide by launching the nationwide "Kevadon Hospital Program," for the purpose of "selling them [doctors] on Kevadon." The instructional manual, only recently accessed by

Plaintiffs' counsel, told Merrell detail men that in addition to "selling" doctors on thalidomide, they were to assist the company in accumulating clinical reports on Kevadon's *indications* (but not its side effects or safety considerations), and to "perfect and develop the best possible detail story for the national introduction of Kevadon."

80. According to that instruction manual, which Merrell distributed at a meeting of its detail men in or around October 25, 1960, OB-GYN departments were identified as a "prime target" of the Kevadon Hospital Program, where interest was noted as being "high." The program was a success; according to Merrell's detail men, the real (but false) "hooker" with those doctors was "Kevadon's lack of toxicity."

81. Merrell told its detail men that its "clinical trials" were not being conducted as "basic clinical studies" because thalidomide's safety, dosage and usefulness had been "firmly established." While Merrell management viewed the publication of results as "all well and good," the detail men were instructed to tell the physician "investigators" that they "need not actually report results if they don't want to." Instead, the goal was to establish "local studies whose results would be spread among hospital staff members." Following these instructions, Merrell detail men represented to doctors that there was no need to adhere to the typical formalities by actually making reports about their findings because Merrell had already "firmly established the safety, dosage and usefulness" of thalidomide, and had already conducted the "basic clinical research" necessary.

82. Contrary to the story it would tell the public for years, Merrell did not distribute thalidomide for a "clinical trial" at all. No study designs were created, no placebos were provided as controls, and "investigators" were told that they need not keep records or make reports. Informed consent was not obtained.

83. Additionally, according to other newly-accessible documents, the Merrell "clinical trial" did not terminate when a particular point in the research endeavor had been reached; instead, the program ended when the FDA approved the drug for sale, allowing Merrell to begin charging for the drug instead of providing it at no cost.

84. The purpose of the Kevadon Hospital Program was not to develop scientific knowledge about the drug, it was to solicit the help of medical opinion leaders–hospital directors and the "most influential physicians"–in developing positive word of mouth about the drug that Merrell hoped would generate a built-in demand once the drug was approved for sale. It was a marketing program, not a research trial.

85. And as a marketing effort, the Kevadon Hospital Program was acknowledged as a success inside the company. Though medical director Bunde would later tell the public on July 28, 1962 that Merrell never "sold" thalidomide in the U.S., what he did not reveal was that at least 2.5 million pills had been distributed to over 20,000 patients by more than 1200 clinical "investigators" in Merrell's bogus "clinical trial" program.

86. The public was unaware of the allegations that Merrell had conducted a fake "clinical trial," however. Though investigations were conducted, they were closed to the public, as was the evidence considered. The public was left with Merrell's version of events, and Merrell maintained consistently that its clinical trials were "straightforward scientific inquiry."

87. Once its NDA was on file, Merrell had an obligation to alert FDA and its clinical investigators/physicians when it received new information about side effects or efficacy. Though reports of side effects, including polyneuritis, continued to mount, Merrell did not disclose them to doctors or their "clinical trial" participants. Nor did Merrell ever disclose that thalidomide had not been tested on pregnant animals, or that it posed a threat to the fetus, due to its chemical composition or the side effects it caused.

88. In fact, when the European thalidomide birth defects became public, Merrell would affirmatively misrepresent what it knew about risk to the fetus. Medical Director Bunde would tell the readers of *Life* magazine in August 1962 that the company had not perceived even a "whisper of suspicion from anywhere in the world that the drug could affect the unborn."

89. In fact, Merrell received a letter inquiring about the fetal risk less than three months after filing its NDAs. That letter, received in the late fall of 1960, was from a Dr. E.B. Linton, who wrote Merrell specifically asking whether Kevadon could affect the fetus. By letter dated December 5, 1960, Merrell employee, Dr. Thomas L. Jones responded to Linton, telling him that the answer to his question had "not been established," even though scientists had known for years that a substance like thalidomide, with a molecular weight of less than 1000, would cross

the placental barrier. Dr. Jones also assured Linton that Merrell "felt" that Kevadon would be "completely safe" for the developing fetus.

90. Merrell had no scientific basis for the assurances it provided to Dr. Linton. To the contrary, it knew or should have known by 1958 that thalidomide could cross the placental barrier and that its known effects in adults, particularly its ability to depress the thyroid and cause nervous system damage, signaled a threat to a developing fetus. And of course, had Merrell bothered to follow up on the pregnant women included in its own "clinical trials" since May 1959, it would have learned for certain that these women were giving birth to malformed babies. Had it pressed Grünenthal or SKF for answers, it would have learned that thalidomide had caused human birth defects.

91. While Bunde told the public in July 1962 that Merrell had no suspicions that unborn babies were at risk, he contradicted that statement years later. According to documents housed in a German archive and accessed only this year, Dr. Bunde later stated that Merrell suspected all along that thalidomide might be a threat to the fetus: "I would say we always were aware of this [risk to the fetus] and concerned as a possibility. I believe the procedure of the thinking that we had then, which was probably universal, was to simply look for any such thing when it was used in a human."

92. Plaintiffs' counsel has also recently obtained what is believed to be the first translated copy of the indictment lodged against eleven Grünenthal employees by German prosecutors in 1968. That document reveals that a Dr. Stevenson, employed by Merrell's

Philadelphia-based subsidiary, the National Drug Company, wrote to Grünenthal itself at the end of February or the beginning of March, 1961, asking whether thalidomide could cause negative impacts on the developing fetus. Grünenthal's Dr. von Schrader-Beielstein replied to Dr. Stevenson on March 23, 1961, informing him that Grünenthal had no "empirical knowledge" about that issue, but suggesting that animal experiments "might be useful."

93. Merrell, however, never conducted such "useful" animal studies, even after the FDA's Frances Kelsey notified the company that its thalidomide application would not be considered complete until such data had been submitted.

94. Instead of conducting studies, doing follow-up with its own "clinical trial" subjects, requesting such data from Grünenthal and its co-licensees, or consulting the documents on polyneuritis risk that its own Dr. Gustav Martin had reviewed in 1959, Merrell went to Grünenthal for answers in March 1961. Merrell executive, Dr. Joseph Murray traveled to Germany, and no later than March 30, 1961, he reported to Kelsey –and, upon information and belief, clinical investigators/physicians--that while thalidomide did cause neurological symptoms, these effects were "low" and "rapidly reversible."

95. Murray must have known this statement was false because Grünenthal had been told by many German neurologists, including Dr. Voss, by this time that the effects were irreversible. As Plaintiffs' counsel has recently learned after review of what is believed to be the first English-language translation of the German judgment handed down against

Grünenthal's executives, the *irreversibility* of the neuropathy caused by thalidomide is its defining characteristic; most other cases of polyneuritis heal over time.

96. Grünenthal, however, did conduct at least one animal study to investigate whether thalidomide was causing polyneuritis. In May 1961, researchers administered thalidomide to chickens in an effort to detect neuropathic effects, and according to Grünenthal, that study demonstrated that chickens injected with thalidomide showed no signs of nerve damage. However, Grünenthal had actual knowledge that its chicken studies were not reliable for assessing polyneuritis risk.

97. Merrell also should have known that the chicken study was not well suited to revealing neuropathic effects, but it did nothing to check or confirm Grünenthal's results. Instead, it submitted the chicken study to the FDA and, upon information and belief, to its clinical investigators/physicians as evidence of safety, and was still relying on that study in September 1961. Upon information and belief, Merrell did *not* submit to the FDA or its clinical investigators/physicians the three articles published in the German and Dutch medical literature in July 1961 alleging that "there can be no longer any doubt that Contergan forte causes 'toxic polyneuritis,'" and concluding that this polyneuritis "is certainly largely unrelated to dispositional and other exogenous factors – and not even the result of overdosing," and that "permanent damage will have to be expected."

98. As for the pregnancy safety data, though it would have been a simple matter for Merrell to provide such data, it failed to do so. Merrell never conducted reproductive animal

tests before news of the European birth defects was release. Nor is there any evidence that Merrell attempted to do systematic follow-up on all of the pregnant women who had taken thalidomide in its "clinical trial" since at least May of 1959. If it did such follow-up, it concealed the results.

99. Merrell did turn to one of its clinical trial investigators to write up a paper on women taking thalidomide in the last trimester of pregnancy only, a time at which the fetus is far less vulnerable to harm. Having designed a study intended *not* to identify a birth defect hazard, Merrell was not disappointed in the results.

100. For that data, Merrell's Medical Director, Dr. Raymond Pogge, again approached its local clinical investigator, Dr. Raymond Nulsen. Dr. Nulsen published the results of a "study" done of women taking thalidomide in late pregnancy—when the fetus is far less vulnerable-- in the June 1961 issue of the *Journal of Obstetrics and Gynecology* in an article entitled "Trial of Thalidomide in Insomnia Associated with the Third Trimester." Nulsen's conclusion was that "no danger to the baby existed from thalidomide."

101. Not only was Nulsen's study poorly designed, but his scientific work was sloppy. The publications referenced as support for his conclusions—German language studies he could not read—did not even involve study subjects who were pregnant, and the records that Nulsen said he relied upon for the article were destroyed.

102. Unfortunately, sloppy scientific work was not the worst flaw in the Nulsen paper. The worst flaw was that he was not, in fact, the author. Those honors went to Dr. Pogge, as confirmed in Dr. Pogge's deposition, recently accessed in a German archive.

103. Though the "Nulsen" paper was published in mid-1961, it was actually completed by February 1960, and Merrell has admitted that it circulated the paper to regulators and others to support its claims that thalidomide was safe for use during pregnancy. Upon information and belief, Merrell submitted the "Nulsen" paper to physicians and clinical investigators, presenting it as the scientific basis for safety claims made for the use of thalidomide in *all* stages of pregnancy. Because Merrell responded to FDA's requests for evidence that the drug was safe for use during pregnancy by supplying the paper written by Nulsen, a paper which only involved subjects given the drug during the third trimester, the FDA would later tell the public that Merrell's clinical trials only *involved* pregnant women in the latter stages of pregnancy. Upon information and belief, this confusion was fostered by Merrell and shared by Merrell's clinical investigators/physicians.

104. When FDA wanted to conduct its own follow-up of Merrell's work, Merrell blocked that attempt by refusing to timely disclose its complete list of "clinical investigators." Though Dr. Kelsey specifically requested that list on February 23, 1961, Merrell provided her with a list of only a small fraction of investigators. It would withhold the complete list until April 1962.

105. Had FDA performed its own follow-up of Merrell's "clinical trial" patients, there is no doubt it would have discovered that Merrell's "clinical trial" patients were giving birth to malformed babies. And the American public would have learned much earlier that thalidomide was causing birth defects, and that it was causing them in the U.S., not just Europe.

106. Merrell, however, would tell the public that it timely complied with the FDA's request. In a July 28 1962 public statement, Bunde told the press that Merrell "cooperated" with the FDA and provided the agency with a list of its investigators "last April," implying that Merrell's cooperation had been full and prompt. Bunde conceals that the FDA first asked for that list at least *14 months earlier.*

107. Merrell also withheld its knowledge that Grünenthal had recommended that thalidomide be placed on prescription due to the polyneuritis side effect, something Merrell learned by letter dated June 13, 1961. Nor did Merrell disclose what Plaintiffs' counsel has recently discovered in German archival documents--that an increasing number of German doctors, unsatisfied with the move to put thalidomide on prescription, were calling for a complete withdrawal of thalidomide from the market, and that Grünenthal faced 89 compensation claims by the end of October 1961, with damages in these cases estimated by Grünenthal's management at five million Deutsche marks or more.

108. Merrell continued to conceal the severity of the polyneuritis threat throughout 1961. In September 1961, Merrell obtained an additional briefing on the polyneuritis effects from Grünenthal, a briefing also attended by representatives from its UK and Swedish licensees.

Here, Merrell reported that its own clinical researchers had observed cases of polyneuritis, and that other licensees had seen more than 100 cases of polyneuritis By the end of 1960, Grünenthal had accumulated 1600 reports that thalidomide was causing polyneuritis in adult patients, but it–like Merrell--was still marketing the drug as non-toxic.

109. Upon information and belief, Merrell never disclosed what it learned about the severity of the polyneuritis threat at this September 1961 meeting, but would instead deny any knowledge of health risk. In an August 10, 1962 letter that Merrell Vice President, Frank Getman wrote to "All Physicians" to give them "the facts about thalidomide and our clinical investigation of it," Getman said that Merrell had every reason to believe that thalidomide was "nontoxic," prior to its receipt of the first report of congenital malformations in late November 1961.

110. Merrell did not warn that the polyneuritis might signal a threat to the fetus. Instead, it continued to put intense pressure on the FDA to approve its thalidomide NDAs. In fact, Merrell enlisted the help of Grünenthal doctors von Schrader-Beielstein and Leufgens, who traveled to America to advise Merrell between September 10-16.

111. Nor did Merrell alter its drug marketing campaign, which was directed in large part by Grünenthal, even when FDA continued to find Merrell's proposed labeling insufficient insofar as it related to use during pregnancy. Worse yet, during September, Merrell sent advertising material to the Canadian market, and, upon information and belief to the American "clinical investigators" which explicitly indicated that thalidomide was suitable for treating

sleepnessless during advanced pregnancy, material that cited the fraudulent Nulsen study as supporting evidence.

112. In late November, 1961, the German-language newspaper *Welt am Sonntag* printed a story revealing that German physician, Dr. Widukind Lenz suspected that thalidomide was responsible for the significant increase in birth defects that had been seen in Germany since the time that thalidomide was distributed in that country. Grünenthal had initially refused to act on his allegations, which it had learned about days earlier. While it finally withdrew the drug on November 26, it explained the decision as one driven by "press reports" that undermined any further scientific discussion. This is the message Grünenthal passed to its licensee companies including Merrell on November 27.

113. Merrell continued to distribute thalidomide, taking the position that Grünenthal's decision was premature, something it told Dr. Kelsey that in November, 1961. Upon information and belief, it also took that position with clinical investigators/physicians, and the public.

114. Merrell informed FDA that it had sent a letter its "active" investigators in early December 1961 to inform them not to dispense the medication to pregnant women. Similar letters were sent to Canadian physicians. Because FDA believed that Merrell's December 1961 letter had, in fact, gone to all investigators, it reported to the public in well-publicized remarks that Merrell had acted "promptly" upon receipt of the birth defect news from Germany.

115. What the FDA and the public would not learn until later, was that the December 1961 letters were only sent to about 10% of Merrell's team of "clinical investigators." Worse, its "warning" letter disputed that any causal connection between thalidomide exposure and birth

defects had been established, the tack taken by both Grünenthal and Distillers as well, and a theme that Merrell would continue to present in the aftermath of the thalidomide tragedy.

116. Merrell subsidiary, the National Drug Company also sent a letter to some number of its investigators on January 11, 1962. Again, however, the company would dispute the causation evidence, stating that Dr. Lenz himself had emphasized that a causal relationship between thalidomide exposure and birth defects had "in no way been established." The letter did not mention that reports published in the January 6 and February 3, 1962 issues of *The Lancet* described the evidence in support of the causal connection as "overwhelming."

117. Merrell finally stopped selling thalidomide in Canada on March 3, 1962, and it withdrew its U.S. New Drug Application on March 8, 1962. However, it waited until March 20, 1962 to send two different letters to the majority of its investigators, counseling them to return or destroy any remaining stocks of thalidomide. Upon information and belief, the letters were not presented in a form that would have distinguished it from any of the mass of advertising materials, and they were likely to have been thrown away. In the course of its follow-up investigation, the FDA learned that many doctors never saw any of this warning information from Merrell.

118. The March 1962 letters were also ineffective as warnings because like the December 1961 letter, they downplayed the risk of injury.

119. Merrell not only downplayed the risk with doctors, but it embarked on a public relations campaign with SKF and Grünenthal. The goal was to assure the public that it had

behaved responsibly in its testing and marketing of thalidomide, and that the drug posed no threat here because of its limited "clinical trial" distribution.

120. Bunde represented the company's position by disputing that thalidomide was even responsible for many of the European birth defect cases. In a public statement made July 28, 1962, he told the public that published studies examining the European cases revealed that half of the mothers with malformed babies hadn't even taken thalidomide. Bunde made substantially similar remarks to Congress on May 24, 1962, and in an August 1962 article published in *Life* magazine. This statement was intentionally misleading; as Bunde knew, the German study he referenced excluded women who had not taken the drug on doctor's orders—unlikely in a country where the drug was sold over-the-counter.

121. Bunde also attempted to reassure the public that the drug had been adequately tested before being distributed. In a statement given to Congress in May and June 1962, he assured Congress that it could be confident that the drug had been "rigorously" tested because an editorial in the Canadian Medical Association Journal said so.

122. Bunde also told Congress that by the time Merrell filed its New Drug Application with the FDA, animal and human studies conducted by Merrell and others "indicated no serious toxicity." He concealed the fact that the 1959 thalidomide syrup studies killed the laboratory animals. Bunde added that the offspring more than 1500 rats that Merrell tested as of June 1962 were born "without evidence of malformation," falsely insinuating that Merrell conducted these reproductive animal tests *before* distributing thalidomide to pregnant women.

123. Merrell's Dr. John Chewning told the press that thalidomide was believed to be the "safest thing since water" in the early days. Vice-President Getman wrote a letter to "All Physicians" in August 1962, assuring them that Merrell had been confident the drug was safe because researchers had never been able to establish an acutely toxic dose for the drug ("LD-50") in lab animals.

124. In fact, retired Merrell Vice President Dr. Claude Griffin gave an interview in 2011 in which he stated that the company did its own testing of thalidomide on thousands of animals, "at different stages of gestation," tests that revealed "there wasn't one single mutation or defect. Not a single one." Like Bunde, Griffin falsely insinuates these tests were conducted *before* Merrell distributed the drug to pregnant women.

125. Bunde also took steps to downplay the company's role in distributing thalidomide in North America. For example, in testimony provided to Congress on May 24, 1962 and re-submitted on June 11, 1962, Bunde stated that "thalidomide was never sold in the United States." Upon information and belief, this statement was false. At best, it was intentionally misleading, since Bunde knew that at least 2.5 million doses of thalidomide had been *distributed* to approximately 20,000 patients by more than 1200 doctors.

126. Bunde's misrepresentation was effective. Even noted pediatrician Dr. Helen Taussig, when writing in *Scientific American* later that summer, noted that "thalidomide-containing drugs did not reach the market in the United States."

127. Bunde also told the public in a July 28, 1962 public statement that Merrell had never recommended to anyone that thalidomide be used for the nausea of pregnancy.

128. In early 2011, retired Merrell Vice President Claude Griffin gave an interview to a senior correspondent at a health issues website, worldhealthnet.com, telling him that Merrell either *warned* of the risks or told physicians that the drug was *not* to be used with pregnant women as part of its "standard operating procedure."

129. The Bunde and Griffin statements were false. Merrell's "Kevadon Hospital Program" specifically instructed Merrell's detail men to target OB-GYN departments in their marketing of the drug. Moreover, Merrell's brochures, distributed to physicians and submitted with its New Drug Application, suggested that the drug was especially useful for pregnant women, specifically for the treatment of nausea in pregnancy. And its medical director, Dr. Raymond Pogge, specifically asked clinical investigator Nulsen to use the drug for the treatment of the early nausea of pregnancy on March 20, 1960.

130. Bunde also attempted to reassure the public by misrepresenting Merrell's conduct after the European birth defects were publicized. The *Boston Globe*, covering Bunde's July 28, 1962 public statement, reported that Merrell had made "a massive effort to recall all supplies of the drug after it first received reports from Europe indicating that the drug caused malformations in babies." Bunde also told the public that Merrell *immediately* notified investigators "active" in the program that thalidomide was not indicated for pregnant women as soon as the company received notice of the "first reports of adverse reaction" from Germany in November, 1961.

131. Bunde's comments were echoed by Merrell Vice President, Frank Getman, in an August 1962 letter to "All Physicians." Getman's letter was intended to give doctors Merrell's version of the "facts about thalidomide." Getman told doctors that "subsequent" to the first

reports of congenital malformations, Merrell "vigorously pursued a course that is in the best interests of the public welfare."

132. Getman also stated that Merrell had undertaken a "thorough" program to assure that clinical investigators disposed of their drug supplies, and that it had provided the FDA with a full list of its investigators in April 1962.

133. What Bunde and Getman conceal and misrepresent is that after Merrell received news of the European birth defects on or about November 29, 1961, it did virtually nothing to notify 90% of its American researchers about the risk until March 20, 1962. Neither reveal that by late July 1962, Merrell had yet to establish any contact with almost 150 of its clinical investigators. Neither reveal that Merrell had done no outreach to "clinical trial" study subjects, to warn them of the risk of continuing to take thalidomide. And neither reveal that Merrell refused to give FDA a complete list of its "clinical investigators" for 14 months before releasing it in April 1962.

134. Relying on Merrell's representations, however, the FDA's public statements praised the company for acting "promptly" to notify its clinical investigators.

135. Merrell's inability to locate about 150 of its investigators almost eight months after learning about the European birth defects was the result of its shoddy record-keeping program, another fact it concealed. Upon information and belief, Merrell executives told the FDA and its participating clinical investigators/physicians that it was confident that it had notified all investigators because it kept very "careful" records. FDA officials would later conclude Merrell's Vick Research Division used inventory control forms that were "functionally

useless" and that there was reason to have "doubts about the adequacy and effectiveness of the procedures followed" by Merrell as it conducted its thalidomide notification actions. This conclusion was never the subject of media reports.

136. According to documents accessible for the first time in English, Grünenthal exercised significant control over the marketing message conveyed by its licensees, including Merrell. The company focused on ensuring that its licensees did not make statements or admissions about drug products that would harm Grünenthal's business interests. According to documents located in a German archive only weeks ago, Grünenthal's licensing agreement with Merrell contained a secrecy clause which prohibited Merrell from publishing scientific information or making any other disclosures that would be detrimental to Gruenenthal's interests, at least after the agreement expired. Upon information and belief, this secrecy clause obligated Merrell to conceal and obscure Grünenthal's involvement in the marketing and manufacture of thalidomide for the North American markets, and to make false statements about what the companies knew about the hazards of thalidomide and when they knew it.

137. Merrell's campaign was effective and continuing. As Merrell Vice-President Getman was to inform all of the doctors distributing the drug–doctors that Merrell knew would be the direct contact with the families of any injured babies--Senator Humphrey told the Associated Press in July 1962 that Merrell had acted "responsibly throughout," and had "complied with every regulation." To this day, FDA and other public sources state that only 17 babies were born with thalidomide injuries in this country due to the "clinical trial" distribution, with about half of these mothers obtaining their thalidomide in Europe. And to this day, public

healthcare websites continue to repeat the Merrell-generated myth that the company acted responsibly by testing the drug on pregnant animals before testing it on pregnant women and that it warned physicians not to use experimental drugs on pregnant women.

Drug developer and manufacturer Grünenthal, a Nazi-lead company whose motto was to "succeed at any cost," knew that thalidomide could cause birth defects by 1956

"If I was a medical practitioner, I would no longer prescribe Contergan today. Gentlemen, I am warning you–I do not wish to repeat an earlier dictum–I'm seeing very grave dangers."

–Dr. Heinrich Mückter, Grünenthal Medical Director

(July 14,1961)

138. To this day, thalidomide developer and manufacture, Grünenthal, publicly maintains that even though it did all of the testing available and indicated in the 1950s, there was no way it could have perceived the birth defect risk before November 1961. However, as evidence that came out decades after the drug was released confirms, Grünenthal was not ignorant of the birth defect risk before releasing thalidomide for commercial distribution, and it did not conduct any prior testing on pregnant animals.

139. In fact, Grünenthal would have learned that thalidomide causes birth defects by Christmas Day, 1956, when an earless baby girl was born to the wife of a Grünenthal employee who had taken thalidomide during her pregnancy. Nor was this baby girl the only thalidomide baby born to Grünenthal's employees. According to a 1975 Helen Taussig oral history interview unearthed only in the last few weeks, Grünenthal had seen at least "a few" cases of phocomelia–

the "flipper limbs" characteristic of thalidomide exposure--among the babies born to its employees.

140. Instead of following up on these cases, Grünenthal released thalidomide for over-the-counter sale in October 1957 and began licensing it for use worldwide. Grünenthal advertised the drug as "completely harmless" and "atoxic," and as the best drug that a pregnant woman could take because it "does not damage either mother or child." It required that its licensees spread the same message, and controlled much of the marketing function for them.

141. What has also been learned only recently from new research not yet published was that the employees that made this reckless decision—the employees to whom Grünenthal entrusted decisions about drug marketing, product safety, and warning-- were Nazi doctors that Grünenthal recruited and hired in 1946, just after the war.

142. Grünenthal's ties to the Nazi party date back to the period before WWII. Grünenthal was founded by the Wirtz family, which also owned the cosmetic, soap and perfume concerns, Dalli-Werke and Maurer & Wirtz. Hermann Wirtz, who was in charge of Grünenthal when it marketed thalidomide, founded the Nazi party chapter in Aachen, Germany. During the war, both Dalli-Werke and Maurer & Wirtz–two other Wirtz family enterprises-- confiscated businesses owned by Jews, and used slave labor to run their factories; both were compelled to pay compensation for those actions after the war.

143. After the war, the Wirtz family founded Grünenthal to market antibiotics. Hermann Wirtz, who was in charge of Grünenthal when thalidomide was developed and sold,

recruited and hired charged and/or convicted Nazi war criminals to serve as scientific staff at Grünenthal, a policy never disclosed to outsiders.

144. Dr. Otto Ambros–convicted of mass murder and enslavement–became a director of the company at some time between 1954 and 1960. When Nazi Drs. Heinz Baumkotter and Ernst Gunther Schenck were released early from a Soviet prison in 1956, Wirtz hired both of them; Baumkotter had served as chief medical officer at the Sachsenhausen camp and as staff doctor at the Mauthausen camp, while Schenck had experimented on prisoners at both Dauchau and Buchenwald. No later than 1960, Wirtz hired Martin Staemmler to head the pathology department at Grünenthal. Though never charged with war crimes, Staemmler had been a leading proponent of the Nazi's racial hygiene program and worked to implement the Third Reich's deportation and Germanization policies after the invasion of Poland.

145. But one of Wirtz's first hires was Dr. Heinrich Mückter, who worked as the company's scientific director beginning in 1954. Mückter had been charged by the Polish government for his involvement in the typhus experiments conducted at the Krakow camp.

146. Plaintiffs have recently obtained what is believed to be the only English-language translation of the indictment filed against Mückter and other Grünenthal executives by German prosecuters in 1968; this document confirms that Mückter was in charge of drug product launches, authorizing and implementing any recalls which might have been required, developing the text of product advertisements, inserts and usage instructions, and he was also instrumental in any decisions to sell a particular drug on prescription. In addition to his annual compensation, Mückter received a bonus or royalty on each dose of thalidomide sold.

147. Under the leadership of these doctors, Grünenthal developed a pattern of rushing drug products to market without conducting sufficient pre-market animal and laboratory tests–of using the customer as a test animal. The company was criticized for this practice in the marketing of its antibiotic drugs, Supracillin and Pulmo 500. Both caused significant side effects, and both were rushed to market before sufficient animal testing or clinical trials were completed. This pattern was repeated with thalidomide.

148. Grünenthal was well aware that releasing drugs for human use before adequate animal tests had been concluded was a violation of medical research ethics. In 1931, Germany had enacted a statute prohibiting human experimentation in advance of comprehensive animal testing, and in the absence of informed consent. These same principles were embraced in the Nuremberg Code.

149. To this day, Grünenthal maintains that it conducted adequate tests before releasing thalidomide for use by the public, and that it conducted all of the tests that were standard and indicated at the time. The truth is that like SKF and Merrell, Grünenthal conducted *no* reproductive animal studies before distributing thalidomide, and licensing it for distribution in other countries. Such tests were conducted by other drug companies; both Merrell and SKF conducted reproductive tests when developing other drugs, including Thorazine and MER 29/triparanol.

150. Nor did Grünenthal conduct adequate chemistry and laboratory tests; its laboratory studies on the chemistry of thalidomide were so rudimentary that the company was unable to determine how the drug was metabolized in the body.

151. The precise scope and nature of Grünenthal's pre-release testing of thalidomide is not known, however, because in 1959, Grünenthal destroyed its testing records.

152. Not only did Grünenthal fail to conduct adequate testing, but it ignored indications that thalidomide posed a specific risk to the developing fetus, and it failed to warn about them. It ignored, for example, the fact that its employees' wives were giving birth to malformed babies after taking thalidomide.

153. If the experience of its employees was not sufficient notice of the risk, documents recently accessed at a German archive confirm that Grünenthal was aware and concerned that thalidomide posed a potential risk to the developing baby by 1957, before the drug was released for commercial sale in any country. On July 5, 1957, Grünenthal physician, Dr. von Schrader Beielstein asked a Dr. Siebke, tenured professor in gynecology and the director of the University Women's Clinic in Bonn, to conduct a clinical trial on pregnant women for the company. Dr. von Schrader Beielstein had himself worked at the university, and was aware that academics there were conducting studies on the effect that medications might have on an unborn child. Nothing ever came of this request.

154. Dr. von Schrader Beielstein would have seen an article on the topic published in "Munich Week" in 1956 by Dr. Siebke's son-in-law, Dr. Josten, an article that stressed that "we know that the unborn child can be harmed by medication administered to the mother," a risk that is particularly high during the first weeks of pregnancy, when the mother might well not even realize that she was pregnant. Dr. Josten's article referenced a bibliography listing 90 relevant publications on the topic of the risk posed by medication taken by a mother during pregnancy.

Grünenthal did not begin to investigate the question of fetal risk until September 1961, when the company asked Dr. Josten to research the issue of fetal risk.

155. Grünenthal also knew that thalidomide could affect the nervous system. As its early patent applications indicate, the company had conducted tests revealing that thalidomide affected the autonomic nervous system and metabolic rate. Both of these conditions might pose a risk to the fetus since thalidomide crosses the placental wall.

156. Though it had done no reproductive animal testing and little laboratory testing, Grünenthal commenced human clinical trials in 1954-1955. Grünenthal's early clinical investigators told the company that thalidomide caused harmful side effects at a Grünenthal-sponsored "Thalidomide Symposium" held on December 15, 1955. There, clinical investigators, including Drs. Jung, Gottschick, Vorlaender, Baumann, Kloos and others, told Grünenthal that thalidomide caused tremor, vertigo, nausea, dizziness, drowsiness and neurological problems, and that it also depressed the basal metabolic rate, an indicator that the action of the thyroid gland is being depressed. The indication that thalidomide caused side effects was confirmed in a report given to Grünenthal by another clinical investigator, Dr. Ferdinand Piacenza, in late 1955 or early 1956; Dr. Piacenza reported that his patients were unable to tolerate the drug at all, requiring early termination of the study.

157. That thalidomide could depress the thyroid was of special significance because it had long been known that hypothyroidism during pregnancy can cause birth defects. This finding should have put Grünenthal and each of its licensees on notice that further investigation into the issue of whether thalidomide might harm the fetus was required. But while Grünenthal

recognized this as a "delicate" issue, it took no such steps. Instead, it sought to downplay and suppress the information.

158. At the outset, Grünenthal simply ignored the evidence of anti-thyroid activity and released thalidomide for sale in October 1957, advertising it as safe and harmless, especially for pregnant women. Grünenthal's 1956 informational brochure, distributed to doctors and pharmacists, acknowledged that thalidomide could affect the thyroid, but it downplayed the significance of this admission by suggesting that the effect might be favorable.

159. In January 1958, two of Distillers' clinical researchers published a paper in the *British Medical Journal*. The authors, Drs. Murdoch and Campbell, concluded that thalidomide depressed the thyroid gland at a dose of 100-200 mg., which is the dose range found by Merrell researcher, Dr. Louis Lasagna, to be necessary for the drug to induce sleep. Though both Distillers and Grünenthal received the report of Murdoch and Campbell, and knew that these two researchers had called for further extensive testing before the drug was marketed, neither company heeded that recommendation.

160. Upon receiving a draft of the paper, Distillers' Dr. Walter Kennedy wrote to Murdoch to ask him to "delete or modify" a perceived slight to thalidomide included in the paper, a request that was apparently heeded, at least in part. Distillers then requested that endocrinologist Dr. Raymond Greene give a comment on the Murdoch and Campbell paper. Three days later, Dr. Greene obliged, firing off a letter stating that the "preliminary" results of his own research indicated that thalidomide had a "negligible" effect on the thyroid," and characterizing certain of Murdoch and Campbell's comments as "unfair." Drs. Greene and

Farran soon published a paper stating that Murdoch & Campbell had been "overly pessimistic," and that any effect on the thyroid was "negligible."

161. Since its licensee had procured a favorable study to undermine Murdoch and Campbell, Grünenthal changed its informational brochure in April 1958 to indicate that the effect Murdoch and Campbell had observed was not, in fact, a sign of a direct effect on the thyroid gland at all. Furthermore, documents recently accessed at a German archive reveal that Grünenthal omitted all mention of the Murdoch and Campbell paper from the marketing brochures prepared for at least some of its licensees. Grünenthal took no further action to determine whether the several findings that thalidomide could influence the thyroid also suggested that it could pose a threat to the developing fetus.

162. Grünenthal also refused to investigate or warn about the neurological findings noted by its early clinical investigators, even though Heinrich Mückter had concluded by April 3, 1956 that "overdosage" on thalidomide could interfere with the adult nervous .

163. Like thyroid depression, the nerve damage finding is significant because the adult nervous system is notably resistant to nerve damage. By contrast–as Dr. Kelsey's own experiments with quinine demonstrated in the 1940s–the fetal liver is much less effective at processing toxins, leaving the fetus far more vulnerable to toxic insults. Taken together with the knowledge that thalidomide would cross the placental barrier because of its low molecular weight, the fact that thalidomide posed a neurological risk was information that would have alerted a toxicologist practicing in the 1950s that the fetus was at risk.

164. Grünenthal, however, did not disclose that thalidomide caused neurological effects, and it did not conduct additional laboratory, animal, or controlled clinical trial tests to determine whether thalidomide would also harm the fetus. Instead, Grünenthal's 1956 *Basispropsekt* advertisements stated that even overdosage did *not* provoke any toxic reaction.

165. The company's September 1957 Grünenthal sales memorandum set forth the sales policy for marketing thalidomide; it stressed that the theme of the thalidomide promotional efforts was to be that the drug was "completely non-poisonous" and "completely safe," "completely innocuous," "completely atoxic," "fully harmless," "astonishingly safe," and a drug that can be taken "at higher doses" without danger.

166. Grünenthal's 1957 advertisements and sales policy documents, including a letter sent to 200,000 doctors and 50,000 pharmacists, advertised thalidomide as "completely non-poisonous" and "completely safe." These phrases were eventually included in 50 advertisements in major medical journals, in letters sent to 200,000 doctors, and in mailings sent to 50,000 pharmacists. During the spring of 1959, Grünenthal sent a letter to all German doctors in free practice stating that even in the event of overdosage and prolonged medication, the drug's effectiveness was not impaired by unwanted side effects, in direct contradiction to Heinrich Mückter's April 3, 1956 admission that overdosage over a long period of time could interfee with the adult nervous system.

` 167. In August 1958, Grünenthal instructed its sales staff to emphasize the drug's "atoxicity," meaning that there was no need for doctors to exercise "continuous control over

consumption." Grünenthal took this aggressive marketing position because it maintained that it was impossible to find an acutely toxic dose that will kill test animals—an LD 50.

168. But Grünenthal—like Merrell—knew that thalidomide did have an LD-50. By March 1958, Grünenthal's Dr. Werner informed Mückter that a more chemically-soluble form of thalidomide might result in a lethal dose. This supposition was confirmed in 1959 when animal studies conducted by both Distillers and Richardson Merrell confirmed that the liquid form of thalidomide was lethal when administered to test animals. Distillers disclosed its findings to Grünenthal and upon information and belief, Merrell did as well. Nevertheless, all three companies continued to claim that thalidomide simply did not kill the test animals, and that there was no LD-50 for the drug.

169. And by August 1958, Grünenthal should have learned that additional malformed babies were being born to women taking thalidomide. By that time, at least one, if not two, malformed babies had been born to women participating in the U.S. clinical trials conducted by SKF. But again, Grünenthal concealed the information and, upon information and belief, warned no one, including its own licensees.

170. Recently-obtained information also reveals that a Turkish virologist named Dr. S.T. Aygün discovered in 1958 that thalidomide had teratogenic properties through experiments on tissue cultures–another type of animal experiment that neither Grünenthal nor its licensees conducted. Aygün determined that thalidomide posed a risk to the fetus and reportedly informed Grünenthal of his findings. Grünenthal is reported to have told Aygün that its own experiments on 3000 animal showed no such effect, concealing the fact none of those 3000

animals examined were offspring born to thalidomide-exposed mothers. Grünenthal neither acted upon nor disclosed Dr. Aygün's findings.

171. Additional newly-discovered information also indicates that in 1958, Dr. Randolph Riemschneider, a German researcher living and teaching in Brazil, conducted experiments on tadpoles. Dr. Riemschneider soon learned that administration of thalidomide to tadpoles caused malformations, and he reported this finding to Grünenthal on June 1, 1959. Grünenthal never followed-up on Dr. Riemschneider's research, nor did it disclose his findings.

172. Instead, Grünenthal concealed those findings even as it began to receive queries from German doctors about whether thalidomide might cause birth defects. As documents recently accessed in a German archive reveal, in 1959, a German gynecologist named Dr. Kreideweiss asked a Grünenthal sales representative named Mannheim whether thalidomide could cause birth defects because his wife had just given birth to a malformed baby after taking the drug. Instead of disclosing the Aygün or Riemschneider findings, Grünenthal assured him that it could not.

173. According to those same documents, on November 24, 1960, Grünenthal was contacted by a German pharmacist named Koch, who wrote the company to ask whether Contergan might cause birth defects. Koch had been consulted by a patient whose wife had given birth to a malformed baby after taking thalidomide. Instead of looking into the matter or disclosing the Aygün and Riemschneider findings, Grünenthal doctors Werner and Sievers wrote Koch a letter on December 2, 1960, cautioning him against assuming any causal link between observed birth defects in a newborn and the mother's ingestion of thalidomide.

174. In July 1961, Dr. Hansle, head of the gynecology department at the Heilbronn hospital, asked Grünenthal whether thalidomide could cross the placental barrier. Although it had been well-established since the 1940s that substances with a molecular weight of less than 1000 could pass the placental barrier, Grünenthal doctors Werner and Sievers, knowing that thalidomide's molecular weight was 258, told the Heilbrunn doctor that "On the basis of experience obtained so far we should like to say that there is no evidence that Contergan passes the placental barrier to the foetuses."

175. This inquiry was followed by a similar one, directed to the company by Ms. Hypia, a Finnish saleswoman, who also asked whether thalidomide could cross the placental barrier, and, if it could, whether it could harm the developing child. Dr. Mückter told Ms. Hypia that it was "unknown" whether thalidomide could cross that barrier, and "unlikely" to harm the fetus if it did.

176. Grünenthal never disclosed any of the information it received indicating that thalidomide could pose a threat to the fetus, and never conducted its own reproductive testing to investigate further. Instead, it marketed thalidomide as safe, particularly for pregnant women.

177. Though Grünenthal had ample warning by 1958 that thalidomide could cause malformations in humans and test animals, in August 1958, Grünenthal's sales staff was still being instructed to emphasize the drug's "atoxicity," meaning that there was no need for doctors to exercise "continuous control over consumption."

178. On August 1, 1958, Grünenthal's Dr. Werner sent a letter to more than 40,000 general practitioners in Germany, representing that the company's thalidomide drug, Contergan,

was the best drug to be administered to pregnant and nursing mothers because it "does not damage either mother or child." Grünenthal based this assertion at least in part on the work of a Dr. Blasiu, even though Grünenthal knew that Dr. Blasiu's study did not, in fact, feature pregnant women as study subjects.

179. The company also sent a letter to all pharmacists in West Germany, informing them that thalidomide was so atoxic that it can be administered to newborns and infants. On or about June 22, 1959, Grünenthal distributed to its field representatives an "emphatic" recommendation that gynecologists had purportedly given to its thalidomide product, Contergan. Grünenthal also sought to target the OB-GYN market by taking out an advertisement for Contergan in a magazine for obstetrics and women's health in January 1959.

180. In its August 1959 promotional brochure, Grünenthal stated that Contergan (thalidomide) "was especially suitable" for pregnant women, and in an August 1960 informational brochure, Grünenthal continued to recommend the drug for use with pregnant women. At the direction of Grünenthal's Dr. Kelling, Grünenthal sales representatives were still touting that thalidomide could be administered by mothers-to-be without concern in the summer of 1961.

181. Upon information and belief, Grünenthal sent the same information to its licensees, and insisted that they use it in their thalidomide marketing campaigns. Grünenthal exercised direction and control over the marketing message used for thalidomide worldwide, and prepared promotional materials for its licensees to use at its headquarters in Germany.

182. Consistent with its clear intent to market thalidomide for use during pregnancy, the August 1959 brochure prepared by Grünenthal for the foreign markets listed gynecology as a specific area of indicated use. It also made the specific allegation that the administration of thalidomide even when there are complications during pregnancy did not lead to additional pathological changes of organ functions.

183. Grünenthal continued to advance the theme that thalidomide was safe and effective for use during pregnancy during 1960. Beginning no later than 1960 and continuing through 1961, Grünenthal represented in its publication, *Compendium,* that thalidomide was indicated for the treatment of the nausea seen in the early stages of pregnancy. This publication was sent to thousands of German doctors. The company's August 1960 informational brochure continued to contain positive statements about taking Contergan for complications during pregnancy, assertions it had made in past brochures.

184. In its April 1961 directive to licensing partners, which would have included Merrell, Grünenthal's Dr von Schrader-Beielstein stated that "We don't want to expand yet again on the indications of thalidomide as a hypnotic drug used in...gynaecology and obstetrics…because they are sufficiently known to you from our documentation."

185. Grünenthal's marketing message did not change in response to the inquiries and information it received about a pregnancy risk, and it did not change even as it received further confirmation that thalidomide caused serious neurological side effects in adults. By July 1959, UK licensee, Distillers, reported that patients taking thalidomide had experienced dizziness and rashes. A Grünenthal sales representative Johannes Zila received a report from a Dusseldorf

pharmacist indicating that one customer had complained that he developed numbness after taking the drug. Later that year, Pharmakalor AG of Basle, Switzerland wrote to Grünenthal, informing the company that 20 well-known Swiss doctors had informed Pharmakalor that patients taking even *one* tablet of thalidomide suffered from "considerable sickness," involving trembling of the hands; the letter concluded by stating that thalidomide was a "terrible drug."

186. By 1959, German doctors, including neurologist Dr. Ralph Voss, began to report to Grünenthal that patients on thalidomide were developing a severe form of nerve damage called polyneuritis, or peripheral neuropathy. Grünenthal's response to Dr. Voss's October 1959 is believed to be typical; the company told him that no one had ever reported such effects, but that it would pay "appropriate attention" to the problem. Grünenthal did not follow-up, and never provided an adequate warning of the risk.

187. Dr. Voss and other physicians reported many more such cases at a conference in Dusseldorf held in the spring of 1960, and Grünenthal sales representatives began to receive demands that thalidomide be placed on prescription. Grünenthal responded by stating that "everything must be done to avoid this." Dr Mückter, who received a bonus based on the volume of thalidomide sold, opposed placing the drug on prescription and made efforts to "nip [the prescription requirements] in the bud."

188. Though Grünenthal did not disclose it, the feedback it was receiving in other countries was also negative by 1960. There were so many reports of side effects amongst the people of Ceylon (now Sri Lanka) that Grünenthal's Ceylonese distributor advised it to voluntarily recall the drug. Grünenthal's Portugese licensee, Paracelsia, discouraged Grünenthal

from even filing an application to distribute the drug with regulatory authorities in that country because Grünenthal's research in relation to thalidomide was so "paltry and incompetent." Upon information and belief, both Greece and France also refused to license the drug in this time frame. By the spring of 1961, Grünenthal not only knew that the FDA was unwilling to rubbert-stamp its data, it knew that the East German government had refused to approve the sale of thalidomide because of its reported side effects and the inadequacy of its safety testing. While Grünenthal was in a position to know *all* of these facts, upon information and belief, it did not disclose them to licensees, and it certainly never disclosed them to doctors or patients.

189. Between July and October 1960, Grünenthal paid 30,382 visits to doctors to downplay the risk of side effects, but at no time before November 1960 did the company change its label to warn against this effect. The strategy of Mückter and the other Grünenthal executives was to "fight for Contergan to the bitter end."

190. In order to pacify doctors and public health officials, Grünenthal finally disclosed the polyneuritis side effect in a label released in November 1960. However, the new label stated that polyneuritis developed only in certain predisposed patients. Grünenthal knew it had no scientific support for the suggestion that polyneuritis was an "allergic" reaction; its Dr. Gunther Sievers conceded as much in a January 1961 letter to Professor Custodis, a Dusseldorf academic. Grünenthal's new label also stated that any such "allergic" reactions would disappear upon the drug's withdrawal. This statement was contradicted by the many reports of permanent polyneuritis that Grünenthal had received from German neurologists. Grünenthal did send a

letter to German physicians about polyneuritis in February 1961, but the entire first half of the letter was comprised of positive statements about the drug.

191. Although Grünenthal had received more than 1600 complaints of other side effects by late 1960, including irreversible nerve damage in adults, it is believed to have concealed much of this information from licensees like Merrell. For example, in December, 1960, Grünenthal wrote a letter to the subsidiary, the William S. Merrell Company, falsely claiming that it had heard of only one case of polyneuritis in 1960.

192. Grünenthal was still marketing the thalidomide as non-toxic. Not only did physicians and patients not know about all of the side effects being reported to Grünenthal, but they did not know that the company used a highly misleading test for ”toxicity.“ Grünenthal deemed a drug to be non-toxic if animals injected intraperitoneally with one milliliter of thalidomide did not die within 48 hours, no matter what other symptoms the animals may have exhibited.

193. Grünenthal did not simply conceal what it knew about thaliodmide’s side effects, it took the offensive, attempting to suppress the publicity of negative publications about its thalidomide drug products. In late 1960 and early 1961, Grünenthal personnel also began visiting public health officials to convince them that the attacks on thalidomide were being driven by jealous competitors. For example, in April 1961, Grünenthal’s Drs. Nowel and Oswald visited the Health Departments of the Ministries for Interior Affairs to persuade them that Contergan was “as good as nontoxic,” that side effects had practically never occurred, and that “rumors” of side effects were probably the result of consumer confusion.

194. In a further attempt to deflect criticism, Grunenthlal's sales staff tried to confuse doctors about thalidomide's side effects, as indicated by a report prepared by Grünenthal's Dr. Goeden after a February 23, 1961 meeting at the university clinic in Cologne. And Grünenthal also urged its sales staff to downplay physician concerns about side effects by suggesting that the entire problem was the result of a campaign initiated by jealous competitors.

195. Instead of conducting scientific tests to investigate the polyneuritis complaints or changing their packaging and labeling information to report polyneuritis as a side effect, another facet of Grünenthal's plan to keep thalidomide in the hands of customers and off prescription was to solicit physicians to publish favorable studies in the medical literature, and to take steps to suppress the publication of unfavorable reports.

196. For example, Grünenthal wrote to its Portugese licensee, Firma Paracelsia, asking it to procure studies for "quick publication...with the reports of fifteen to twenty successful cases who have tolerated the drug well...." This type of study, Grünenthal stressed, was "more important to us than a broadly based, large work that will not appear for eight to twelve months. From this, you can see what kind of testers we have in mind." And in July 1961, Grünenthal circulated to "co-workers worldwide" the work of Singapore researcher, David Chou, insisting it stood for the proposition that pregnant women tolerated thalidomide well. The Chou paper, however, did not even establish when, for how long, or *whether* pregnant women had taken the drug.

197. Grünenthal was also successful in advancing the publication of a paper by a Dr. Winzenried from Hamburg in the medical journal, "*Medizinische Klinik*" [Medical Clinic]. This

paper contained notable inaccuracies, omissions and inconsistencies, but was widely touted by Grünenthal. Although Wizinreid later updated the paper to reveal that he *had* seen patients with thalidomide-induced polyneuritis, that fact was never communicated or revealed by Grünenthal.

198. Instead, Grünenthal continued to promote the Wizinreid paper as evidence of thalidomide's safety. Grünenthal also paid the expenses so Dr. Wizinreid could take a trip to the U.S. and Canada and promote the ideas in his paper. Grünenthal continued to use his paper to promote thalidomide even after he advised them that he had eventually observed peripheral nerve damage in his patients after Contergan use.

199. Grünenthal's licensees, who took their marketing marching orders from Grünenthal, made similar efforts to pad the medical literature with favorable studies. As described above, when Merrell was under pressure from the FDA to produce evidence that it was safe to administer thalidomide to pregnant women, it procured a fraudulent studied purportedly authored by Dr. Ray Nulsen but actually written by its own medical director, Dr. Raymond Pogge.

200. By July 1961, Grünenthal's ability to seed the medical literature with positive papers was backfiring, as its hand-picked scientists began to generate negative findings, findings which then had to be concealed. For example, in late 1960, Grünenthal convinced Professor Dr. Max Werner, a leading German allergist practicing at the Pinneberg District Hospital, to investigate whether the polyneuritis that thalidomide users were developing was in fact of an allergic nature, as Grünenthal had been claiming since at least November 1960. After examining several polyneuritis patients, Dr. Werner told Grünenthal that thalidomide

polyneuritis "was definitely not allergically caused." These results were never published and the Contergan label was not changed to reflect this discovery.

201. Grünenthal also suppressed the publication of unfavorable reports authored by independent physicians. In the fall of 1960, Grünenthal intervened with the German medical journal *Medizinische Welt* to delay the publication of an article discussing thalidomide's ability to cause polyneuritis, an article written by Konigstein neurologist, Dr. Frenkel. Grünenthal had already tried to convince Dr. Frenkel himself not to publish, but was unsuccessful. The article was delayed after Grünenthal doctors Kelling and Michaels met with journal editor Dr. Paul Matis, to discuss "preventive measures against the article he has received about Contergan." As a monthly report authored by Michaels later confirmed, the purpose of the Matis meeting was to prevent publication of any articles alleging that thalidomide was not, in fact "completely safe." The article was delayed because was the advertising department objected to publication. Dr. Michaels cautioned, however, that "In the long run we will not be able to stop publication of the side effects of Contergan..."

202. In the spring of 1961, Grünenthal's Dr. Michael also intervened with Dr. Stamm, editor of *Deutsche Medizinische Wochenschrift*, to prevent publication of an article by Dr. Raffauf, an article stating that thalidomide appeared to cause polyneuritis. The article was delayed at Grünenthal's request.

203. Grünenthal also continued to conceal and misrepresent the facts to licensees, including Merrell. For example, although several noted neurologists, including but not limited to Drs.Voss and Laubenthal, had informed Grünenthal that thalidomide-induced polyneuritis was

irreversible, this is not the message that Grünenthal passed along to Merrell executives in March 1961. After consulting with Grünenthal, they returned to report to Dr. Kelsey that the polyneuritis was "rapidly reversible."

204. As stated above, Grünenthal did sponsor one animal study in search of ammunition with which to combat the allegation that thalidomide was causing polyneuritis. In May 1961, chicken tests commissioned by Grünenthal failed to neuropathic effects. However, Munich physician, Dr. Schimert, warned Mückter that the chicken studies did not allow the company to draw *any* conclusions about polyneuritis on June 20, 1961. While Grünenthal communicated the "positive" results from its chicken study to Merrell by telegram of May 16, 1961 and letter dated May 25, 1961, it never disclosed to Merrell the caveats expressed by Dr. Schimert a month later.

205. Instead, Grünenthal continued to rely on the chicken study and to urge its licensees to do the same. It did *not* draw their attention to the three articles published in the German and Dutch medical literature in July 1961 alleging that "there can be no longer any doubt that Contergan forte [thalidomide]causes 'toxic polyneuritis,'" and concluding that this polyneuritis "is certainly largely unrelated to dispositional and other exogenous factors – and not even the result of overdosing," and that "permanent damage will have to be expected."

206. By June of 1961, another 100 German doctors had contacted Grünenthal to report cases of nerve damage; by that month, it had received complaints from 1300-1400 practitioners. It was also receiving hundreds of reports of other side effects; in the month of June *alone*, Grünenthal received 500-600 side effects reports, including some in children. Nevertheless,

when Munich pediatrician, Dr. Eichmann, contacted Grünenthal's Munich sales representative, Mr. Czech, to ask for information about Contergan [thalidomide], Czech "mentioned that there were no reports on Contergan damage in children neither in Germany nor abroad."

207. In addition to receiving thousands of polyneuritis complaints, 90-100 cases of thalidomide addiction were reported by July 1961. Nevertheless, Grünenthal was to tell Kaiserslautern pharmacist Bock on July 19, 1961 that *no* cases of addiction had been observed. By July, 1961, the foremost nerve damage experts in Munich, Vienna, Frankfurt/Main, Darmstadt and Essen were demanding that Grünenthal withdraw thalidomide from the market immediately. None of these facts were ever disclosed by Grünenthal, but have only recently come to light in documents that have been housed in a German archive.

208. A June 7, 1961 report of medical sales representative Dr. Sipple informed Grünenthal management that German doctors believed that the company was "advertising irresponsibly" and that in their view, "it is irresponsible to dispatch samples ….it would be preferable to pay more attention to the seriousness of the side effect."

209. A physician/expert for Grünenthal's own insurance carrier named Dr. Scheid informed the company representative, Dr. Huber, on June 9, 1961, that: " Damage after Contergan [thalidomide] use is a regular occurrence. The damage is irreversible. The patient information leaflet about Contergan is totally inadequate in his opinion. It was providing too little clarification and omitted to mention the level of severity of possible damage." On June 19, 1961, the insurance company, acting on behalf of Grünenthal, contacted Dr. Scheid again to

obtain further elaboration on his views about Contergan, receiving the following reply: ""The advice in the latest Contergan brochure is totally inadequate."

210. On June 13, 1961, Grünenthal informed Merrell that it would ask the government of North Rhine-Westphalia to place Contergan on prescription, but that it was not doing so because of side effects. Grünenthal's public message would be that it feared the drug would be discredited by bad outcomes resulting from improper and unauthorized use. Adhering to its contractual obligation, Merrell (and other licensees like Distillers) kept this information to itself.

211. Though the news Grünenthal received in June 1961 was undoubtedly negative, its representative, Dr. Winandi, sent a new promotional letter to pharmacists that month, touting Contergan's "worldwide acceptance" and its "unusually low toxicity." Upon information and belief, Grünenthal provided the same reassuring message to its licensees.

212. Grünenthal consistently concealed the seriousness of the polyneuritis threat, and continued to market the drug as practically harmless and practically atoxic. But it also continued to ignore the threat to the fetus, while targeting the drug for use with pregnant women. Recently-obtained documents confirm that in the summer of 1961, Grünenthal continued to advertise that the drug was specifically indicated for use in pregnancy. Those documents indicate that the company's advertising campaign–under the direction of Mückter–was also not changed even though the subject of thalidomide's ability to cause embryopathy had become the subject of extensive discussions at Grünenthal by May 1961. In fact, by April of 1961, Grünenthal scientists –including Dr. Michael–were beginning to inform management that

thaliodmide might interfere with the activity of B vitamins, the deficiency of which was known to cause birth defects.

213. In the summer of 1961, Grünenthal retained Dr. Kemper, a member of the pharmacology department at Munster, to conduct some animal experiments. Kemper's preliminary findings of August 1961 revealed that thalidomide caused malformations to develop in the chicken embryo. Grünenthal concealed Dr. Kemper's findings.

214. By July 1961, Grünenthal began to hear from its lawyers. According to the criminal indictment that has only recently been translated into English, on July 10, Grünenthal's legal department sent management-- Hermann Wirtz, Jacob Chauvistré and Drs. Mückter and Leufgens–a six-page memorandum informing them that it was "obvious" the company was liable for contributory negligence with respect to the polyneuritis claims, and that given Grünenthal's "culpability," the company would be ill-advised to litigate the cases instead of settling them.

215. By July 14, 1961, even Heinrich Mückter could see the writing on the wall; he stated at an internal company meeting that if he were a doctor, he would not prescribe Contergan because he saw "grave dangers."

216. Nevertheless, in its July 1961 compilation prepared for use by licensees like Merrell, Dr. von Schrader Beielstein continued to emphasize that thalidomide's most striking feature was its safety, and that it was therefore safe for use by gynecological patients, as expressed to licensees in previous communications. Grünenthal continued to use the word "atoxic" on its package labels, packaging and promotional materials until mid-July at least. Its sales representatives were instructed to point out the "nonexistent hazardousness" of Contergan

well past mid-July 1961. Dr. Von Schrader-Beielstein prepared a circular to go to medical practitioners after the July 14, 1961 meeting, a circular that reemphasized the fact that thalidomide was indicated for use with gynecology and obstetrics patients, and that "the safety of thalidomide is the most conspicuous feature of the preparation." To the extent the polyneuritis or neuropathy was mentioned in labeling information at all, Grünenthal downplayed the hazard, continuing to cite the Wizinreid paper.

217. Although Grünenthal had concealed its knowledge about side effects from licensees like Merrell, that changed no later than August 1961. Minutes of an August 10, 1961 internal Grünenthal meeting attended by Hermann Wirtz, Jacob Chauvistre, Heinrich Mückter and legal counsel, von Veltheim and von Schrader-Beielstein state that "So far doctors abroad have not been informed about Contergan side effects in any way. Three days ago all representative companies were informed about the Contergan situation for the first time…."

218. On July 6, 1961, Walter Hodgetts, a sales representatives for UK licensee, Distillers, was told by Australian physician, Dr. William McBride, that he believed Distillers' thalidomide product, Distaval, was causing phocomelia among babies born at his hospital in recent months. Hodgetts' records indicate that he reported this conversation up the corporate hierarchy. Nothing happened, and Distillers continued to sell Distaval, taking out an ad in October 1961 stating that thalidomide could be administered to pregnant women "without any detrimental effect to mother or child." Distillers did not disclose Dr. McBride's warnings to the public, or to physicians, but it had a contractual obligation to disclose them to Grünenthal and, upon information and belief, it did.

219. On September 1, 1961, Grünenthal changed its product packaging and labeling to reflect the neuropathy risk, but it downplayed that risk and confused doctors and patients by implying that this was an "allergic" reaction, to be suffered by a few, even though Dr. Werner had informed the company that it was not months earlier.

220. As late as October 1961, Grünenthal continued to represent that thalidomide was "harmless." This was true even though by August, the question of whether thalidomide could damage a developing fetus was also openly discussed within Grünenthal. However, Grünenthal continued to conceal these concerns from physicians, the public, and upon information and belief, its licensees.

221. The fact that Contergan was placed on prescription was not disclosed by Merrell to the clinical investigators/physicians, the FDA or the Canadian regulatory authorities, or the public, nor did Merrell ever disclose that an increasing number of German doctors, unsatisfied with the move to put Contergan on prescription, were calling for a complete withdrawal of thalidomide from the market, or that Grünenthal faced 89 compensation claims by the end of October 1961, with damages in these cases estimated by Grünenthal's management at five million Deutsche marks or more.

222. And, as stated above, by September, Merrell was still putting extreme pressure on the FDA to approve the drug even though it had presented no convincing evidence that the drug was safe for the fetus, an effort aided by Grünenthal Drs. von Schrader-Beielstein and Leufgens.

223. In the fall of 1961, Dr. Hermann Brand of Lubeck told a Grünenthal area sales representative that a malformed baby had been born to a patient who had taken Contergan during

her pregnancy, and that he suspected that Contergan had caused the deformities. Mückter told the inquiring doctor that it was simply "unknown" to Grünenthal whether thalidomide could cross the placenta. Though Drs. Werner and Schuppius wanted to research the question, that proposal was rejected by Mückter's research department, causing Schuppius to resign. Grünenthal concealed this information and never warned anyone that it had by now received a number of reports that malformed babies had been born to pregnant women taking thalidomide.

224. By October 1961, Dr. Kemper, the University of Münster researcher studying thalidomide, reported that he had observed malformations in both the bones and the vital organs of chickens given thalidomide. These findings, too, were concealed by Grünenthal.

225. If Grünenthal disclosed the Kemper study to its licensees, that knowledge did not influence their behavior. Distillers, for example, took out an advertisement in October 1961 stating that thalidomide could be administered to pregnant women "without any detrimental effect to mother or child." Merrell continued to press the FDA to approve its NDAs.

226. By October, 1961, a Hamburg pediatrician named Widukind Lenz had discovered that there were likely to have been 50 phocomelic babies born in the Hamburg area, an epidemic. After interviewing mothers and consulting local birth defect statistics, Dr. Lenz began to suspect thalidomide. Lenz contacted Grünenthal to report his conclusions on November 15, but Mückter told him that this was the first report Grünenthal had ever received making any connection between thalidomide and birth defects.

227. On November 20, three Grünenthal representatives--Dr. von Schrader-Beielstein Dr. Gunther Michael, and Grünenthal's lawyer, Dr. Von Voltheim--met with Dr. Lenz. They

attacked his research and threatened him with legal action for the "murder of a drug by rumour." Grünenthal refused to withdraw the drug, but instead sent out 66,957 circulars to German pharmacists and doctors, boasting that thalidomide was a "safe medicine."

228. Grünenthal refused to withdraw the drug a second time at a subsequent meeting on November 24. Mückter was especially opposed to withdrawing the drug, even though he revealed to his colleagues on this date that Distillers had sent him a letter outlining the allegations made by Dr. McBride, which mirrored Lenz's. Despite the fact that two doctors half a world apart had reached the same conclusion, Mückter–who received a royalty on every pill of thalidomide sold by Grünenthal-- still refused to withdraw Contergan from the market.

229. On Noevember 26, the German-language newspaper *Welt am Sonntag* printed a story revealing that thalidomide was suspected to be the culprit in the rash of birth defects that had been seen in the community. Grünenthal withdrew the drug on November 26 not because it conceded that Lenz and McBride were right, but because "press reports" undermined any further scientific discussion. This was its public message , and the one passed to its licensee companies including Merrell on November 27.

230. As stated above, however, Merrell took its cue from Grünenthal and continued to distribute thalidomide in North America, claiming that Grünenthal's decision to withdraw the drug was "premature," and publicly contesting the evidence of causation.

231. After Grünenthal's withdrawal, Merrell, Grünenthal, SKF, and Distillers accelerated the campaign of disinformation and concealment they had participated in while thalidomide was on the market. From the outset, Grünenthal –like Bunde--contested that

thalidomide even caused birth defects, an argument it pursued with vigor when nine of its executives were accused and stood trial for allegedly committing violations of Germany's criminal laws. Grünenthal's Dr. Gunter Sievers publicly took a "diametrically opposed view" of thalidomide causation from that of Lenz and McBride, and published an article making that point in the German medical literature in 1964.

232. Like Merrell and SKF, Grünenthal also maintained that thalidomide had been "most thoroughly studied and the adverse reactions could not be anticipated with the most modern techniques available," remarks Dr. Von Schrader Beielstein made to FDA officials in an October, 1962 interview.

233. Grünenthal –like Bunde--also contested the fact that it ever recommended that the drug be used by women in the early stages of pregnancy. Distillers, too, told the FDA in October 1962 that it never recommended that thalidomide be used to treat the nausea of pregnancy, even though a Distillers' advertisement taken out as recently as October 1961 indicated that "Distaval can be given with complete safety to pregnant women...without adverse effect on mother or child."

234. Grünenthal also misrepresented the results of animal experiments independent researchers conducted after the thalidomide tragedy came to light in Europe. In 1965, for example, Grünenthal executives gave a television press conference stating that the company had never seen any malformations induced in experiments conducted on monkeys, a statement made only weeks after Grünenthal visited a U.S. facility in which thalidomide-exposed monkeys had given birth to malformed infants.

235. Though eleven of its executives were criminally indicted in Germany in 1968, Grünenthal has continued to take the public position that it adequately tested thalidomide before bringing it to market, that it had no reason to suspect that the drug was dangerous, that reproductive testing was in no way indicated, that the company acted promptly upon discovering the hazard, and that it was largely vindicated by the German criminal court.

236. For example, in 2006, Grünenthal authored a misleading document called "The Thalidomide Tragedy," in which it describes--from its own self-serving perspective--the historical events leading up to the birth of thousands of malformed babies. Grünenthal published this document by, among other means, posting it on the part of the company website dedicated to thalidomide. .

237. Grünenthal states, for example, that during development, thalidomide was "subjected to the usual battery of investigations," tests that were "in line with the pharmacological and toxicological investigations carried out in rodents," and that "revealed no signs of risk whatsoever." In fact, Grünenthal saw "no signs of risk whatsoever" because it didn't *conduct* these standard tests and because it ignored the information reported to it

238. Grünenthal states that in the mid-1950s, there were "no guidelines for the development, production and marketing of medicinal products, no uniform federal medicines act, and no licensing authority such as the present Federal Institute for Drugs and Medical Devices (BfArM)," so "it was possible to introduce ....thalidomide on the German market.....without any governmental review of the documentation." This statement is intentionally misleading,

because Germany had enacted a law concerning human experimentation in 1931. In addition, Grünenthal was bound to consider the laws in licensee countries like the U.S.

239. Grünenthal also states in this report that "At that time testing for harmful teratogenic effects was not standard practice and was in no way indicated," though many drug companies–including Merrell and SKF -- *were* conducting reproductive tests on drugs intended for widespread human use.

240. Grünenthal states that it withdrew thalidomide from the German market only 12 days after it became aware of the first "plausible suspicious" that the drug could cause birth defects, but conceals the fact that it had known of the birth defect risk since 1956.

241. Grünenthal states that "it was not until 1964, three years after market withdrawal, that proof of the teratogenic effect of thalidomide was obtained in animal experiments conducted in New Zealand white rabbits. With the laboratory animals routinely used before that time it had not been possible to produce such proof." Grünenthal's UK licensee, Distillers, succeeded in producing malformed rabbit babies in experiments conducted and published in *1962*. Rabbits *were* routinely used in animal tests in the 1950s–in fact, *Grünenthal* had conducted animal tests on rabbits in 1955-6 and Distillers had conducted rabbit tests by 1959. Moreover, Grünenthal's own researcher, Dr. Kemper, was able to produce malformations in chicken embryos in *1961*.

242. Until the fall of 2010, Grünenthal's website stated that the company did not learn that thalidomide could cause polyneuritis until 1960. In fact, Grünenthal knew of this risk by 1959, as confirmed in recently-accessible German court documents.

243. The company's website also alleges that the German criminal judge presiding over the criminal case lodged against its employees actually made a finding that the company's pre-market testing was adequate. Plaintiffs' counsel has obtained what is believed to be the first English-language translation of that judgment in recent months, however, and no such finding was made.

244. Grünenthal's former CEO also helped perpetuate the myth that the company and taken all of the actions that a responsible company would have taken. In a 2007 public statement, Sebastian Wirtz, made a public statement asserting that according to all of the evidence that he'd seen, "there was no way the tragedy could have been averted." This, of course, has been Grünenthal's theme for 50 years, and the theme of its licensees, including Merrell and Distillers. An abundance of evidence now available to Plaintiffs' counsel reveals that Grünenthal knew years before thalidomide was ever sold to the public or distributed in North America that thalidomide could cause birth defects.

The Plaintiff

Glenda Johnson

245. Plaintiff Glenda Johnson was born on November 23, 1962 in Ripley, Mississippi. Her mother suffered from extreme morning sickness during her pregnancy, and was given thalidomide by her doctor, Dr. Orville Stone. She took thalidomide for several weeks during her early pregnancy. Glenda was born with multiple birth defects, including but not limited to esophageal atresia and tracheoesophageal fistula, an imperforate anus with a rectoperineal fistual, absence of the right radius, radial club hand, adduction deformity of the left hand, a

deformed left thumb, scoliosis, syndactyly of the 2nd and 3rd toes bilaterally, a missing ovary, and numbness and tingling in her hands and feet. In addition, Glenda has suffered deterioration in her body.

245A. Plaintiff Steven Lucier was born on August 29, 1961 at the Navy Hospital in Philadelphia, Pennsylvania. His mother took thalidomide during the early days of her pregnancy as a treatment for morning sickness and sleepnessness. Steven was born with multiple birth defects, including but not limited to a malformed left hand, abnormally thin bones in the left arm and hand, a malformed breast plate, and weak facial muscles. In addition, Steven has suffered deterioration in her body.

FRAUD/FRAUDULENT CONCEALMENT
(SMITHKLINE BEECHAM CORPORATION/GLAXO DEFENDANTS)

246. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

247. As alleged with particularity in the Statement of Facts above, SKF fraudulently concealed and misrepresented material facts relating to its use and distribution of thalidomide, its knowledge of the birth defect hazards that thalidomide posed, the knowledge that all Defendants had with respect to thalidomide's birth defect hazard, and the reasonableness of Defendants' conduct. As alleged in particular detail above, SKF engaged in at least the following fraudulent acts:

1) SKF distributed thalidomide to clinical trial subjects while concealing the risk it posed to the fetus from physicians and patients alike, risks that it knew or should have known about no later than 1955. Those risks were known or knowable to SKF because thalidomide had documented antithyroid activity, it was known to cause serious nerve damage in adults, its chemical composition was similar to a known teratogen, and at least one of its metabolites mimicked the B vitamin, folic acid, indicating that thalidomide had the potential to interfere with the metabolism of B vitamins in the body. Because it was known or knowable that thalidomide could cross the placental barrier, all of these conditions indicated that thalidomide posed a threat to the fetus.

2) SKF falsely represented to physicians and its clinical trial patients that prior to being distributed to people for use in therapy or research, thalidomide had been adequately tested in animals, consistent with medical ethics. Further, in August 1962, its President, Walter Munns, issued a public statement on behalf of SKF informing the public that all appropriate tests had been conducted. In fact, no tests on pregnant animals were done prior to thalidomide's distribution, and insufficient laboratory tests on the drug had been conducted, a fact SKF concealed in its public statement.

3) In an August 1962 public statement that SKF intended the press to cover and disseminate to the public, SKF President Walter Munns falsely represented that

animal tests available in the 1950s would not have revealed the birth defect danger.

4) SKF fraudulently concealed the fact that it had conducted human clinical trials in 1956-7, and that at least one, if not two, malformed babies were born to its study participants no later than August 28, 1958. Further, its President, Walter A. Munns lied to Congress about that fact in August 1962, denying that any malformed babies had been born to pregnant women participating in SFK's clinical trial. SKF knew and intended that these public statements would be relied upon and disseminated by the media, and that the public, including Plaintiffs, Plaintiffs' mothers, and their physicans would rely upon them. Similarly, SKF knew that by withholding explosive information about the birth of malformed babies during its clinical trial, the press would be unlikely to report SKF's involvement at all, given the modest size of its disclosed clinical trial, and that the public would be left with *no* information indicating that it had tested thalidomide on humans.

5) SKF fraudulently misrepresented that there had been no hint or suspicion that thalidomide could cause birth defects before news of the European tragedy came to light in November 1961. Specifically, SKF fraudulently concealed the fact that it knew that thalidomide had actually caused birth defects in babies born to women taking thalidomide years no later than August 28, 1958, and it lied about that knowledge in the one public statement made about the SKF clinical trial.

And by 1955, SKF knew or should have known that thalidomide posed a birth defect risk for the reasons stated in subparagraph (1).

6) In its August 1962 statement, "Thoughts on Thalidomide," SKF falsely represented that the thalidomide that had been distributed was promptly recalled upon first receipt of the news that European babies had suffered birth defects caused by thalidomide. SKF concealed the fact that Merrell did nothing to even alert the vast majority of its "clinical investigators" that the drug should not be given to pregnant women for almost four months after learning the news, and even then, the company disputed that there was actual evidence that thalidomide caused birth defects. SKF also concealed the fact that when *it* learned that thalidomide could cause birth defects no later than August 28, 1958, it did *nothing* to recall the drug or alert its clinical investigators or their patients. Instead, it continued to make thalidomide available to those investigators through 1958 at least.

7) Upon information and belief, SKF falsely represented that no toxic dose, or LD 50, had ever been established for thalidomide. SKF continued to falsely represent that it had every reason to believe thalidomide was non-toxic until the time the birth defects came to light.

8) In its August 1962 public statement, SKF falsely insinuated that the only thalidomide birth defect babies were in Europe and Australia.

9) Acting, upon information and belief, pursuant to the advice of Grünenthal, SKF distributed thalidomide in such a manner that it was next to impossible for patients/"clinical trial" subjects to identify the drug they were taking. Doses of thalidomide were distributed without a label, and in many different shapes and sizes.

10) SKF falsely represented that Merrell and other companies distributing thalidomide had acted responsibly in its distribution and recall of thalidomide.

11) SKF concealed the fact that Grünenthal was actively involved in the marketing, promotion and distribution of thalidomide in North America, and it obtained the thalidomide it used in its clinical trial from Grünenthal by virtue of a license or other contractual agreement.

12) Acting in concert with Grünenthal and according to a common plan or design, SKF fraudulently concealed information on thalidomide's risks, particularly its birth defect risk, because it had executed an agreement with Grünenthal prohibiting it from disclosing information harmful to Grünenthal's interests.

13) Upon information and belief, SKF fraudulently misrepresented that thalidomide was safe, harmless and appropriate for use by pregnant women. That being the case, SKF could not have obtained the informed consent of its clinical trial study subjects.

14) In the decades following the news that thalidomide caused birth defects in European babies, SKF has continued to conceal the evidence of its conduct from the public.

248. SKF had a contractual duty of disclosure to Grünenthal. Upon information and belief, the two companies entered into either the Preliminary Licensing Agreement it was SKF's practice to use, or the licensing agreement that it was Grünenthal's practice to use, or both. Both agreements mandated disclosure of findings relating to the drug under evaluation.

249. SKF also had a common law duty of disclosure to Grünenthal. SKF received thalidomide from Grünenthal for the purpose of conducting scientific testing. Scientific tests are done in order to test hypotheses and develop knowledge. Because Grünenthal provided thalidomide to SKF for the purpose of conducting such tests as a prelude to finalizing a licensing agreement, it was entitled to learn the results of the tests, and SKF had a duty to report those results to Grünenthal.

250. SKF knew that Grünenthal relied upon test results when developing its thalidomide marketing message, its sales strategy, its packaging, usage instructions, and its label and warning information. SKF not only had reason to expect that these usage instructions, package inserts, product labels and other information would be communicated by Grünenthal and/or its licensees to doctors and patients, but SKF knew it was *certain* that doctors and patients would rely on this information, and would take action in reliance it. Because SKF suppressed the results revealing that thalidomide could cause birth defects, doctors would continue to prescribe thalidomide to pregnant women like Plaintiffs' mothers, and pregnant women would

continue to take thalidomide in reliance on the false sense of safety created by SKF's suppression of its test results.

251. Further, SKF knew that Grünenthal and its customers, licensees, physicians, clinical trial investigators, and patients had no choice but to rely on its reported results because SKF alone had exclusive control and custody over those results.

252. While all of SKF's tests results would have been material to Grünenthal, any test results indicating that Grünenthal's stated understanding about the drug's safety was incorrect would have been especially significant and material to Grünenthal, its licensees, as well as physicians and patients.

253. Finally, SKF had an absolute duty to disclose the truth about the fact that women participating in its clinical trial gave birth to babies with birth defects when directly asked by Congress to disclose that information

254. SKF fraudulently concealed what it knew about thalidomide's birth defect hazard from Congress, the public, physicians and patients. Upon information and belief, SKF also fraudulently concealed those facts from Grünenthal.

255. SKF knew for certain that a direct and certain consequence of SKF's failure to disclose the birth defect hazard to Grünenthal in 1958 was that an uninformed Grünenthal would not warn of the birth defect hazard, but would instead market thalidomide as safe, particularly for pregnant women, and would distribute the drug without a warning of that birth defect risk.

256. SKF also knew that its intentional suppression of material information about thalidomide's ability to cause birth defects was certain to create a dangerous misapprehension of

the danger on the part of Grünenthal, its licensing partners, physicians, and the public about the safety of thalidomide.

257. Upon information and belief, Grünenthal *did* rely upon SKF's silence in just this way because Grünenthal *did* continue to make such assertions. For example, in 1958, the company wrote a letter to more than *40,000 German doctors,* claiming that thalidomide was the *best* drug to be administered to pregnant women.

258. It was also certain that SKF's suppression of the birth defect hazard meant that if Grünenthal ever selected another company to market thalidomide in the U.S. –which it did only months later when it signed a licensing agreement with Richardson-Merrell– Grünenthal would not possess information about the birth defect hazard to pass along to this licensee, which would also rely on SKF's fraudulent silence when developing its marketing strategy, and when formulating warnings for use by its own clinical investigators, physicians or patients.

259. Merrell did rely on SKF's silence in marketing to pregnant women. SKF provided material assistance to Merrell by standing silent, even though it knew that disclosure of its clinical trial results and animal studies would have caused Merrell to warn *against* the use of thalidomide in pregnant women.

260. SKF President Walter Munns told Congress that SKF reported *all* findings to Grünenthal. Upon information and belief, that statement was false.

261. If true, however, then SKF conspired with Grünenthal to suppress the birth defect hazard information, and to keep it from physicians, patients, and the public, pursuant, upon information and belief, to the secrecy clause in Grünenthal's licensing agreement. SKF knew if

it joined with Grünenthal to suppress the facts about the birth defect hazard, physicians, and patients would justifiably rely on their silence, and would continue to believe that thalidomide was safe and non-toxic for pregnant women.

262. SKF knew it was certain that these babies and their mothers–Plaintiffs here-- were the people who would ultimately and justifiably rely upon the information that SKF chose to disclose or suppress. They are the people that the disclosure requirements were intended to protect. And these Plaintiffs' mothers and their doctors *did* rely on the false sense of safety created by SKF's silence and fraudulent suppression about the facts of the birth defect hazard. Had Plaintiffs' mothers or their doctors known the truth, the doctors would not have prescribed thalidomide to them, and they would not have ingested thalidomide during their pregnancy.

263. As a well-established pharmaceutical company, SKF knew it was certain that physicians and patients would rely on its silence, and knew that Plaintiffs and people like them were certain to suffer harm from its fraudulent concealment. SKF knew that as a direct result of its fraudulent suppression of the fact that thalidomide caused birth defects, pregnant women around the world would continue to take thalidomide, and would continue to give birth to malformed babies. Plaintiffs here were in the specific category of persons meant to be protected by the requirement that clinical findings and test results be disclosed. SKF's suppression of those findings and its refusal to disclose those findings to Grünenthal was a direct cause of their injuries.

264. SKF was under an obligation to disclose the findings of its animal study results and clinical trial results for the benefit and guidance of Grünenthal, its licensees, other

investigators, physicians, and their customers/patients. SKF knew that Grünenthal and its licensees would use and justifiably rely on the reports of SKF's test results when formulating usage instructions, package inserts, product labels and other information intended to inform patients and doctors of the risks and benefits of thalidomide.

265. SKF also knew and intended that in making public statements to Congress, the media, and the public, that those statements would be disseminated by the media and relied upon by the public, including Plaintiffs. By fraudulently concealing the fact that it conducted thalidomide clinical trials on pregnant women for more than 50 years, SKF's actions denied victims the information they needed to ascertain the cause of their injuries. SKF's fraudulent concealment diverted them from any inquiry they could have conducted, and caused them to relax their vigilance. Since there was never any hint that SKF distributed thalidomide in the popular media, there was no reason for victims like the plaintiffs to direct inquiries to SKF.

266. As a direct and proximate result of SKF's fraud and fraudulent misrepresentations and concealments, conduct that was willful, wanton, and reckless, Plaintiff suffered grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses when Plaintiff's mother ingested thalidomide drug products which had been developed, formulated, designed, manufactured, sold, distributed, supplied, marketed and/or promoted, either directly or indirectly, by Defendants.

267. While Plaintiffs have plead their fraud claim with particularity, they allege that because many of the facts relevant to their fraud and fraudulent concealment claim are exclusively within the control of SKF, that a relaxed standard of particularity is appropriate. The

documents relating to SKF's use of thalidomide were, for the most part, never publicly disclosed. Upon information and belief, virtually all of the documents relating to SKF's clinical trial, the results of that trial, and the disclosures made by SKF are within the possession and control of SKF and, possibly, Grünenthal.

WHEREFORE, Plaintiff prays for judgment against SKF in an amount which will compensate the Plaintiff for Plaintiff's injuries, and prays that SKF be estopped from interposing statute of limitations defenses.

FRAUD/FRAUDULENT CONCEALMENT

(MERRELL AND GRÜNENTHAL DEFENDANTS)

268. Plaintiffs repeat, reiterate,and reallege each and every allegation set forth above with the same force and effect as if copied herein.

269. As alleged with particularity in the Statement of Facts above, Defendants fraudulently concealed and misrepresented material facts relating to their manufacture, development, design, testing, marketing, promotion, sale and distribution of thalidomide. They misrepresented and concealed what they knew about the birth defect hazard that thalidomide posed, about the lack of testing that thalidomide underwent before its commercial release, and about the reasonableness of their conduct.

270. As alleged in particular detail above, Defendants engaged in at least the following fraudulent acts:

1) Defendants distributed thalidomide while concealing from patients, clinical trial subjects, physicians and clinical investigators, and the public the risk it posed to the fetus, risks that all Defendants knew or should have known about. Those risks were known or knowable to Defendants because thalidomide had documented antithyroid activity, it was known to cause serious nerve damage in adults, its chemical composition was similar to a known teratogen, and at least one of its metabolites mimicked the B vitamin, folic acid, indicating that thalidomide had the potential to interfere with the metabolism of B vitamins in the body. Because it was known or knowable that thalidomide could cross the placental barrier, all of these conditions indicated that thalidomide posed a threat to the fetus.

2) Defendants falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that prior to being distributed to people for use in therapy or research, thalidomide had been adequately tested in animals. In fact, no tests on pregnant animals were done prior to thalidomide's distribution, a fact all Defendants concealed. Merrell's Dr. Carl Bunde affirmatively implied that Merrell had conducted reproductive tests on pregnant animals before news of the European birth defects became public in 1961. Grünenthal's website affirmatively (but falsely) states that the German court presiding over the criminal case brought against eleven of its executives held that Grünenthal had adequately tested prior to marketing thaliodmide.

3) Defendants falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that animal tests available in the 1950s would not have revealed the birth defect danger.

4) Defendants falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that animal tests on pregnant animals were not "indicated" and were not typically performed in the 1950s by companies intending to distribute drugs they had reason to know would be ingested by pregnant women.

5) Merrell falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that thalidomide was not sold in this country, and that it was distributed only in "clinical trials," concealing the fact that its massive marketing effort was not a "clinical trial" as alleged. Upon information and belief, thalidomide was sold to some patients. Merrell made these representations to convince the public that thalidomide was only available on a very limited basis to research study participants, and to hide the fact that it had engaged in an aggressive marketing campaign to convince doctors to use the drug with patients, resulting in the distribution of at least 2.5 million doses of thalidomide in this country.

6) Defendants fraudulently misrepresented to patients, clinical trial subjects, physicians and clinical investigators, and the public that they did not recommend that thalidomide be used to treat the nausea of early pregnancy. In making these

statements, Merrell concealed the fact that its brochures and NDAs recommended such a use and that its clinical investigators were asked to test the drug in women suffering the nausea of early pregnancy. To this day, retired Merrell executives falsely but publicly maintain that Merrell either warned of thalidomide's risks, or warned that the drug was not to be used with pregnant women.

7) Defendants fraudulently misrepresented to patients, clinical trial subjects, physicians and clinical investigators, and the public that there had been no hint or suspicion that thalidomide could cause birth defects before news of the European tragedy came to light in November 1961. They all fraudulently concealed the fact that all knew that thalidomide had actually caused birth defects in babies born to women taking thalidomide years before that; Grünenthal knew by 1956, and, upon information and belief, Merrell knew no later than early 1960. Further, the FDA's Frances Kelsey raised the suspicion that the fetus might be at risk no later than May 1961. And by 1955, all Defendants knew or should have known that thalidomide posed a birth defect risk for the reasons stated in subparagraph (1).

8) Defendants falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that the thalidomide that had been distributed was promptly recalled upon first receipt of the news that European babies had suffered birth defects caused by thalidomide. They concealed the fact that Merrell did nothing to even alert the vast majority of its "clinical investigators" that the drug should not be given to pregnant women for almost four months after learning

the news, and even then, the company disputed that there was actual evidence that thalidomide caused birth defects.

9) Defendants falsely misrepresented to patients, clinical trial subjects, physicians and clinical investigators, and the public that there was little evidence that thalidomide caused birth defects, and continued to dispute causation for years.

10) Merrell falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that when it distributed thalidomide in the United States, it engaged in a "clinical trial." In fact, its massive distribution effort was a marketing scheme.

11) Upon information and belief, Defendants falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that no toxic dose, or LD 50, had ever been established for thalidomide. Defendants concealed the results of the thalidomide syrup experiments that killed the laboratory animals at doses of 500 mg/kg and 1000 mg/kg, experiments conducted by Merrell and UK licensee, Distillers. They continued to falsely represent that they had every reason to believe thalidomide was non-toxic until the time the birth defects came to light, representations that Grünenthal (at least) continues to make to this day.

12) Acting, upon information and belief, pursuant to the advice of Grünenthal, Merrell marketed thalidomide in such a manner that it was next to impossible for patients/"clinical trial" subjects to identify the drug they were taking. Merrell's Kevadon Hospital program contemplated distribution on a sample basis, and

assured its "clinical trial investigators" (the physicians who treated Plaintiffs' mothers) that it was not necessary to keep records or provide follow-up information or results. Doses of thalidomide were distributed without a label, and in many different shapes and sizes.

13) Defendants Merrell falsely represented to patients, clinical trial subjects, physicians and clinical investigators, and the public that it had acted responsibly and complied with every regulation in its distribution and recall of thalidomide.

14) Defendants concealed from patients, clinical trial subjects, physicians and clinical investigators, and the public the fact that Grünenthal was actively involved in the marketing, promotion and distribution of thalidomide in North America, and that both SKF and Merrell obtained their thalidomide from Grünenthal by virtue of a license or other contractual agreement. Similarly, Merrell concealed the fact that some of the thalidomide distributed in North America was manufactured and distributed without a warning by its own subsidiary, J.T. Baker Company.

15) Defendant Grünenthal fraudulently suppressed publication of medical articles exposing thalidomide's risks and side effects and mandated, through its contractual agreements, that contracting partners like Merrell and SKF refrain from disclosing information harmful to Grünenthal's interests.

16) Defendants fraudulently commissioned articles presenting thalidomide in an unjustifiably favorable light. Merrell presented at least one such study as the

work of one of its "clinical investigators," while in fact the study had been solicited and written by Merrell's own medical director.

17) Merrell fraudulently concealed from patients, clinical trial subjects, physicians and clinical investigators, and the public the fact that it had withheld the identities of the majority of its clinical investigators for 14 months to prevent FDA from exposing the birth defect risk and from exposing the fraudulent nature of Merrell's "clinical trial."

18) Grünenthal fraudulently concealed from patients, clinical trial subjects, physicians and clinical investigators, and the public the fact that it recruited and hired Nazi war criminals to hold positions of authority in its company, and that it allowed some number of them to make decisions concerning the design, manufacture and of thalidomide.

19) Grünenthal has concealed from patients, clinical trial subjects, physicians and clinical investigators, and the public the fact that many German hospitals and several countries refused to permit the distribution of thalidomide due to the shoddy testing and risk of side effects.

20) Defendants misrepresented to patients, clinical trial subjects, physicians and clinical investigators, and the public that thalidomide was safe, harmless and appropriate for use by pregnant women.

21) In the decades following the news that thalidomide caused birth defects in European babies, Defendants have concealed the evidence of their conduct from

patients, clinical trial subjects, physicians and clinical investigators, and the public. Grünenthal has misrepresented the contents of evidence developed during the criminal trial against its executives, German-language evidence that was protected from public disclosure for 10-30 years under German law, leaving Grünenthal's story unrebutted.

271. Defendants had a duty to disclose the truth and to be truthful in statements made to licensing partners, physicians/clinical investigators and the public, and they knew that Plaintiffs' mothers, and the physicians who treated them would rely on their misrepresentations, and on the false sense of security created by their concealment of the knowledge–available to Grünenthal by 1956–that thalidomide could cause birth defects.

272. Defendants concealed and misrepresented these material facts in order to maximize profits and money-making opportunities. They also concealed and misrepresented the facts to prevent thalidomide victims from learning that their injuries were caused by the wrongful conduct of the Defendants, and to prevent them from learning the identities of the actors responsible for their injuries.

273. Defendants were successful in promoting the false and erroneous story that thalidomide was really not present here in meaningful quantities, and that the companies had all acted completely responsibly. For example, relying on Defendants' representations, noted pediatrician, Helen Taussig printed an article in the *Scientific American* stating that thalidomide did not make it to U.S. markets. U.S. Senator Hubert Humphrey told the Associated Press that Merrell had acted "reasonably throughout" and had complied with every regulation. In July

1968, FDA Commissioner George Larrick told the public that no malformed babies had been born in this country save those whose mothers had obtained thalidomide overseas. The U.S. Congress concluded that the thalidomide birth defects was a European problem because Dr. Frances Kelsey had saved U.S .babies. Whether expressed directly by Defendants, or indirectly, by persons relying on Defendant-supplied information, the media reported Defendants' account of the tragedy, and of their conduct.

274. Defendants knew and intended, that in making public statements to Congress and the public, that those statements would be disseminated by the media and relied upon by the public, including Plaintiffs and their mothers, who would conclude that thalidomide could not have caused their injuries because it wasn't present in the U.S. outside limited research studies, and that in any event, no wrong-doing had occurred. Having been denied access to the facts about Defendants' conduct, Plaintiffs did rely upon these misrepresentations and concealments, to their detriment.

275. As a direct and proximate result of Defendants' fraud and fraudulent misrepresentations and concealments, conduct that was willful, wanton, and reckless, Plaintiff suffered grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses when Plaintiff's mother ingested thalidomide drug products which had been developed, formulated, designed, manufactured, sold, distributed, supplied, marketed and/or promoted, either directly or indirectly, by Defendants.

276. While Plaintiffs have plead their fraud claim with particularity, they allege that because many of the facts relevant to their fraud and fraudulent concealment claim are

exclusively within the control of Defendants, that a relaxed standard of particularity is appropriate. The documents relating to Merrell's and Grünenthal's use of thalidomide, the results of their "clinical trials," the internal documents reflecting what the companies knew and when they knew it are virtually all documents that are within the possession and control of Merrell and Grünenthal. Grünenthal has indicated that it has a warehouse containing many thalidomide-related documents, documents that are unlikely to be accessible to the Plaintiffs from any other source. Therefore, they respectfully request that this court apply a relaxed particularity standard to their pleading.

WHEREFORE, Plaintiff prays for judgment against Defendants in an amount which will compensate the Plaintiff for Plaintiff's injuries.

NEGLIGENCE, NEGLIGENT DESIGN,

NEGLIGENT MISREPRESENTATION, and *RES IPSA LOQUITUR*

(ALL DEFENDANTS)

277. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

278. All Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing and sale of thalidomide drug products to ensure the safety of those drug products and to ensure that the consuming public, including Plaintiff, Plaintiff's mother, and her physicians obtained accurate information and instructions for use of thalidomide drug products.

279. All Defendants owed a duty toward foreseeable users of thalidomide drug products to exercise reasonable care to ensure that those thalidomide drug products were reasonably safe for their ordinary and intended uses. Where the risk attendant upon use of thalidomide drug products exceeded the drug's utility, and where safer alternative designs existed, the duty of ordinary care imposed upon Defendants the duty not to market the thalidomide drug products, or to withdraw the product from the market.

280. All Defendants had a duty to adequately test their thalidomide drug products before distributing them to patients, clinical trial subjects, or the public.

281. All Defendants had a duty to ensure through adequate testing, labeling, and otherwise, that physicians and/or clinical trial investigators who were likely to prescribe or distribute the drug for theirs patients'/study subjects' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways. In particular, this duty encompasses the specific duty to test for, and warn about, the risk that thalidomide posed to a developing fetus, a risk that was inherent in the use of the drug during pregnancy. This duty includes a duty to warn of the risks that were known or knowable to the Defendants post-sale or post-distribution, and to exercise ordinary care to ensure that this warning reached physicians who had distributed or prescribed their thalidomide drug products and their patients.

282. In the context of human experimentation or clinical trials, the Defendants' duty of ordinary care included the duty to perform human experiments only after comprehensive laboratory and animal tests had been conducted. In this case, that duty of ordinary care included the duty to test thalidomide drug products on pregnant animals before testing them on pregnant

women. All Defendants engaging in human experimentation or "clinical trials" of thalidomide drug products had a duty to warn the physicians and clinical investigators of the risks and side effects, and to obtain the informed consent of the patients/study subjects after providing them with an adequate warning of the thalidomide drug products' risks and side effects. This duty to warn included the duty to inform physicians and patients that thalidomide drug products had not been previously tested on laboratory animals, and that it had not been tested in controlled clinical trials.

283. In addition to their duty to provide adequate warning of the known and knowable risks, side effects and contraindications of thalidomide drug products, all Defendants had a duty to disclose knowledge of side effects, contraindications and risk information to licensees, licensors, clinical investigators, and suppliers of thalidomide drug products for testing purposes.

284. The dangerous propensities of thalidomide drug products, as referenced above, were known and scientifically knowable to all Defendants, through appropriate research and testing, when they distributed, supplied, sold or licensed thalidomide drug products. Those risks, however, were not known to physicians and clinical investigators who would be expected to prescribe the drug for Plaintiff's mother and other similarly situated patients, and they were not known to clinical trial study subjects or patients, who were entitled to warning information necessary to allow them to provide their informed consent.

285. All Defendants breached their duty of ordinary care and their duty to exercise the care of an expert in the distribution, manufacture, and marketing of their thalidomide drug

products by failing to adequately test those products for side effects in the laboratory, in animals, and in controlled, scientific and reasonably designed clinical trials.

286. All Defendants failed to exercise ordinary care and the care and duty of an expert in the design and formulation of thalidomide drug products, in the testing of thalidomide drug products, in the preparation of adequate warning information, and in the dissemination to physicians, clinical investigators, patients and study subjects of risk and side effect information known or knowable to them.

287. All Defendants failed to exercise the duty of ordinary care by failing to monitor the medical literature and failing to continue testing thalidomide drug products and failing to conduct adequate post-market surveillance so they could provide adequate post-sale or post-distribution warning information. All Defendants breached their duty to warn by failing to provide information to physicians, patients, study subjects, and licensing partners that was accurate, not misleading, and otherwise adequate to allow physicians to make informed choices about the use of thalidomide drug products, to allow study subjects to provide informed consent, and to allow licensing partners to make informed decisions about product labeling, packaging and warning information.

288. Among other non-exclusive specific acts and omissions, all Defendants breached their duty of care by placing into the stream of commerce thalidomide products as a treatment for sleeplessness, nausea or other minor ailments when other existing and safer alternatives were already available as therapy for such ailments. All Defendants breached their duty of care by failing to conduct reproductive tests on animals before testing on pregnant women. All

Defendants breached their duty of care by affirmatively representing that thalidomide had been adequately tested, that it was "completely harmless," "atoxic," and was safe for pregnant women and their babies when they knew or should have known that thalidomide was toxic, that it caused nerve damage in adults and that it caused birth defects in the babies delivered by women who ingested thalidomide during pregnancy. All Defendants breached their duty of care by affirmatively targeting pregnant women when marketing their product.

289. All Defendants failed to exercise ordinary care and the care and duty of an expert in the design of thalidomide drug products. All Defendants breached their duty of care by placing into the stream of commerce and distributing thalidomide drug products to pregnant women and women of child-bearing age when the risk of harm outweighed any possible benefit the drug could offer, and when there were safer alternative treatments for the conditions thalidomide was intended to treat.

290. All Defendants failed to exercise ordinary care when they failed to disclose test results, and knowledge of side effects, contraindications and risk information to clinical investigators, physicians, patients, study subjects, licensees, licensors, clinical investigators, and those supplying thalidomide drug products for testing purposes.

291. All Defendants failed to exercise ordinary care and the care and duty of an expert in manufacturing, selling, supplying, testing, and/or distributing thalidomide drug products into the stream of commerce when all Defendants knew or should have known that thalidomide drug products created a known, foreseeable and high risk of unreasonable and dangerous side effects, including birth defects, when ingested by pregnant women.

292. All Defendants breached their duty of ordinary care and their duty of care as an expert by disseminating warning information to licensees, licensors, physicians, clinical trial investigators, patients and study subjects that was inaccurate, misleading, false, materially incomplete, and otherwise inadequate.

293. In addition to breaching their duty of ordinary care and their duty as an expert by failing to adequately test thalidomide drug products, failing to reasonably design such products, failing to provide adequate warnings about the known or knowable risks and side effects of those products, failing to conduct adequate post-market surveillance, and failing to disclose known or knowable risk and side effect information, all Defendants willfully and deliberately concealed known risk and hazard information and failed to disclose these risks and side effects, and in doing so, acted with willful, wanton, conscious, and reckless disregard for Plaintiff's safety and welfare.

294. All Defendants breached their duty to exercise ordinary care and to act with the care of an expert by failing to provide adequate and accurate information about the known and knowable risks, hazards, side effects and contraindications of their thalidomide drug products to physicians, clinical investigators, licensees and licensors. Instead, they all concealed material information about those known and knowable risks, side effects, hazards and contraindications, and distributed inaccurate and misleading information about those thalidomide drug products, information that failed to warn of known and knowable risks, hazards, side effects and contraindications.

295. When providing inadequate, inaccurate and misleading information to physicians, clinical investigators, licensees and licensors, Defendants knew it was certain that their misinformation would be relied upon by those physicians, clinical investigators, licensees and licensors. Physicians and clinical investigators would make prescribing, testing and distribution decisions based upon the misleading and inaccurate information supplied and/or concealed by the Defendants, while licensees and licensors would rely on that misleading and inaccurate information to formulate usage instructions, packaging, labeling, and warning information, information that in turn would be relied upon by physicians, clinical investigators, consumers, patients and study subjects. All Defendants concealed risk information and provided inadequate warnings knowing and intending that others would rely on this information, and they did so in order to avoid liability for injuries and to make profits from the sale and distribution of thalidomide drug products. This conduct was not only negligent, it was made recklessly and with conscious disregard of the safety of persons like Plaintiffs, and was willful and wanton.

296. Plaintiffs were in the class of persons intended to be protected by this duty of ordinary care and the breach of this duty was a direct and proximate cause of their serious and permanent bodily injuries and consequent economic losses.

297. As a direct and proximate result of Defendants' negligence and of their willful, wanton, and reckless conduct, Plaintiff suffered grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses when Plaintiff's mother ingested thalidomide drug products which had been developed, formulated, designed, manufactured, sold, distributed, supplied, marketed and/or promoted, either directly or indirectly, by Defendants.

298. All Defendants' acts and omissions and concealment of material facts about the negligent design of their thalidomide drug products, and about the risks, hazards, side effects and contradindications of their thalidomide drug products were made with the understanding that licensees, licensors, physicians, clinical investigators, study subjects and patients would rely on them when choosing, prescribing and distributing thalidomide drug products. The economic and physical damage proximately caused by Defendants' conduct and suffered by Plaintiff in this case would not have occurred had Defendants exercised the high degree of care imposed upon them, and would not have occurred in the absence of their negligence. Neither Plaintiff nor Plaintiff's mother was negligent when ingesting thalidomide drug products and no other cause can be identified as a proximate cause of Plaintiff's injuries. Therefore, Plaintiff pleads the doctrine of *res ipsa loquitur*.

WHEREFORE, Plaintiff prays for judgment against Defendants in an amount which will compensate the Plaintiff for Plaintiff's injuries.

NEGLIGENT HIRING
(Grünenthal DEFENDANTS)

299. Plaintiffs repeat, reiterate,and reallege each and every allegation set forth above with the same force and effect as if copied herein.

300. The Grünenthal Defendants had a duty to exercise ordinary care in the hiring and supervision of their employees, officers, and directors. That duty included the duty to hire appropriately-qualified employees, officers and directors, and to supervise and control them, such that their conduct did not create an unreasonable risk of bodily harm to others when those

employees, officers or directors were acting within the scope of their employment, and were using the premises, chattel or business relationships of the employer. This duty applies when the employer both knows he has the ability to control his employee, officer, or director and knows of the need to exercise such control and supervision.

301. In this case, the Grünenthal Defendants knew that there was a necessity to hire appropriately-qualified people, and to provide adequate and reasonable supervision, direction and control over those employees, officers, and directors exercising influence and/or control over the development, design, manufacture, marketing, promotion, sale, or distribution of drug products, including thalidomide drug products. It was known and foreseeable to the Grünenthal Defendants that such supervision, direction and control was necessary to protect the safety of patients, customers, and study subjects ingesting those drug products. Supervision, direction, control, and appropriate hiring was necessary to ensure that the company's thalidomide drug products were reasonably designed, were reasonably safe and fit for their intended use, and that they were marketed with adequate and accurate warnings about hazards, risks, side effects, and contraindications.

302. The Grünenthal Defendants breached this duty when they hired and retained as officers, directors, and/or employees persons who were known to have been active participants in the Nazi prison camp experimentation programs, racial hygiene programs, and forced deportation and "Germanization" programs, including persons who had been charged and/or prosecuted as Nazi war criminals for their actions during WWII. It was known or knowable, and was reasonably foreseeable that such persons would not exercise the care required of a

pharmaceutical manufacturer, designer and seller/distributor when making decisions about product testing, product marketing, and the provision of adequate safety information.

303. Specifically, the Grünenthal Defendants breached their duty of care and were negligent in hiring as an officer, director, or employee the following non-exclusive list of persons:

1) Dr. Otto Ambros, who had been convicted of mass murder and enslavement after the war, and who, upon information and belief, became a director of the company at some time between 1954 and 1960.

2) Martin Staemmler, head of Grünenthal's pathology department beginning no later than 1960. Though never charged with war crimes, Staemmler had been a leading proponent of the Nazi's racial hygiene program and worked to implement the Third Reich's deportation and Germanization policies after the invasion of Poland.

3) Dr. Heinz Baumkotter, former chief medical officer at the Sachsenhausen camp and as staff doctor at the Mauthausen camp.

4) Dr. Ernst Gunther Schenck, who had experimented on prisoners at both Dauchau and Buchenwald.

5) Dr. Heinrich Mückter, who became Grünenthal's scientific director in 1954. Though he avoided prosecution, Dr. Mückter had been charged and sought by the Polish government sought for his participation in forced typhus "experiments" at the prison camp in Krakow.

304. The Grünenthal Defendants breached their duty of care by hiring these people, who were known to have been trained to sacrifice human safety in pursuit of other goals. The Grünenthal Defendants breached their duty of care by hiring such people and providing them with authority to make decisions concerning the manufacturing, design, development, formulation, sale, promotion, marketing, and distribution of thalidomide drug products. They also breached their duty of care by concealing the material fact that such persons had been hired as officers, directors and employees from licensing partners, physicians, and the public. Such conduct was not only negligent, it was willful, wanton, reckless and exhibited a conscious disregard for the safety of patients, customers and study subjects ingesting their thalidomide drug products.

305. The Grünenthal Defendants' breach of their duty of ordinary care, and their negligence, and willful and wanton conduct was a direct and proximate cause of Plaintiff's grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses.

WHEREFORE, Plaintiff prays for judgment against Defendants in an amount which will compensate the Plaintiff for Plaintiff's injuries.

CONCERT OF ACTION
(ALL DEFENDANTS)

306. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

307. The failure of all Defendants to adequately test thalidomide drug products, to design them so they were reasonably safe and fit for their intended use, to provide adequate warning information and to disclose material known and knowable facts about the risks, hazards, side effects and contraindications of thalidomide drug products was tortious, in that it was negligent, willful and wanton, and reckless, and fraudulent.

308. Each Defendant's failure to disclose the known and knowable facts about the risk thalidomide drug products posed to the developing fetus was also part of a common design and plan, implemented, at least in part, through the licensing agreement that, upon information and belief, Grünenthal insisted that licensing partners and those obtaining supplies of thalidomide for testing purposes execute. Upon information and belief, that agreement required that the Defendants, each and every one of them, disclose to Grünenthal scientific information learned about the risks, benefits, and side effects of thalidomide drug products, but that they refrain from disclosing scientific and other information detrimental to the interests of Grünenthal. It was Grünenthal's motto to "succeed, whatever the cost," and its agreements and directions to licensees were all designed to achieve that goal by maximizing sale of thalidomide drug products, even at the risk of human health and safety.

309. Additionally, each and every Defendant acted according to a common design and plan to withhold from the public, including physicians, patients, facts about the known and knowable risks and side effects of thalidomide drug products in a conscious and joint effort to maximize sales of thalidomide drug products. Such a plan or design would not be effective unless all manufacturers, seller, distributors, licensees, and licensors of thalidomide drug

products actively participated in the concealment of risk, side effect, and hazard information that might decrease thalidomide sales. Disclosure by any one of them would thwart the others' efforts to maximize sales by concealing hazard information from physicians, clinical investigators, patients/study subjects and the public. Upon information and belief, Grünenthal exercised significant supervision and control over the marketing of thalidomide in all licensee countries, including the U.S. and Canada, and insisted that its licensees follow its direction, actions the licensees took in hopes of securing increased profits from thalidomide drug sales.

310. Not only did all Defendants act according to a common plan or design, but each of them provided substantial assistance to the others in the commission of the tortious acts of marketing a negligently designed and untested product that lacked an adequate warning. By way of example only and not limitation, SKF provided substantial assistance to both Grünenthal and Merrell when, knowing that thalidomide caused birth defects, it stood silent as both companies intentionally targeted pregnant women in their marketing of thalidomide products, and as they each represented that the drug was "completely safe" and appropriate for use by pregnant women, specifically for the treatment of the nausea of pregnancy. Grünenthal provided substantial assistance to SKF and Merrell when it failed to disclose to them (or to allow them to disclose) its knowledge that thalidomide caused serious nerve damage and birth defects, knowing that if they possessed that information, they would be obligated to disclose it to physicians, clinical trial participants and patients/study subjects. It also provided substantial assistance to SKF and Merrell when it failed to disclose the known and knowable hazards of thalidomide drug products to the public, patients/customers, and physicians/clinical investigators. Had

Grünenthal made such disclosure of the facts known and knowable to it, neither SKF nor Merrell would have been able to distribute thalidomide without providing a warning that the drug had not been adequately tested in pregnant women, that it caused nerve damage in adults, and that it caused birth defects, and both would have been exposed to tort liability for their failure to warn. Conversely, Merrell provided substantial assistance to Grünenthal and to SKF when it failed to disclose the known and knowable hazards of thalidomide drug products to the public or to physicians/clinical investigators. Had Merrell made such disclosure of the facts known and knowable to it, Grünenthal would not have been able to distribute thalidomide without providing a warning that the drug had not been adequately tested in pregnant women, that it caused nerve damage in adults, and that it caused birth defects, and both Grünenthal and SKF would have been exposed to tort liability for the injuries caused by their distribution of thalidomide without conducting adequate testing and without providing an adequate warning.

311. Each Defendant provided substantial assistance to the others by suppressing, concealing, and misrepresenting what they knew or should have known about the birth defect hazard posed by thalidomide and about the drug's lack of testing, and/or by affirmatively representing that the drug was safe for pregnant women and that it had been adequately tested, knowing that the concealment and misrepresentation of that information by each and all of them constituted a breach of the duty of ordinary care. Further, when suppressing, concealing, and misrepresenting what they knew or should have known about the birth defect hazard posed by thalidomide and about the drug's lack of testing, and/or by affirmatively representing that the

drug was safe for pregnant women and that it had been adequately tested, each Defendant and all of them committed a tortious act by breaching their own duty of care to the Plaintiff.

312. Defendants' misrepresentation of the risks and hazards of thalidomide, their misrepresentation of the extent to which thalidomide had been tested, and their concealment of the known and knowable hazards that thalidomide posed to the developing fetus was negligent, and was also willful, wanton, conscious, and reckless disregard for Plaintiff's safety and welfare.

313. As a direct and proximate result of Defendants' acting in concert to fulfill a common plan to conceal the hazards of thalidomide, and of their willful, wanton, and reckless conduct, Plaintiff suffered grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses when Plaintiff's mother ingested thalidomide drug products which had been developed, formulated, designed, manufactured, sold, distributed, supplied, marketed and/or promoted, either directly or indirectly, by Defendants.

WHEREFORE, Plaintiff prays for judgment against Defendants in an amount which will compensate the Plaintiff for Plaintiff's injuries.

CIVIL CONSPIRACY
(ALL DEFENDANTS)

314. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

315. The failure of all Defendants to adequately test thalidomide drug products, to design them so they were reasonably safe and fit for their intended use, to provide adequate warning information and to disclose material known and knowable facts about the risks, hazards,

side effects and contraindications of thalidomide drug products was tortious, in that it was negligent, willful and wanton, and reckless, and fraudulent.

316. In addition to committing overt and intentionally tortious acts as alleged above, each and every Defendant acted together and agreed and conspired to commit the torts of fraud and misrepresentation by executing a common design and plan to jointly withhold from the public, including physicians, and patients, facts about the known and knowable risks and side effects of thalidomide drug products in a conscious and joint effort to maximize sales of thalidomide drug products. Such a plan or design would not be effective unless all manufacturers, seller, distributors, licensees and licensors of thalidomide drug products actively participated in the concealment of risk, side effect and hazard information that might decrease thalidomide sales. Disclosure by any one of them would thwart the others' efforts to maximize sales by concealing hazard information from physicians, clinical investigators, patients/study subjects and the public. The Defendants participated in this conspiracy to commit fraud and misrepresentation knowing that it would lead to an increased incidence of death, and of serious and permanent injuries, including birth defects.

317. Upon information and belief, Grünenthal exercised significant supervision and control over the marketing and distribution of thalidomide in all countries, including those where direct distribution occurred through a third party like SKF, Merrell or Distillers. It prepared marketing brochures, provided expert witnesses, and provided scientific studies upon which licensees were to rely when developing warning and promotional materials and when applying for authority to sell the drug in their respective countries. Upon information and belief,

Grünenthal insisted that licensees bring products to market in a short period of time, a requirement that forced them to rely heavily on the scientific work that Grünenthal conducted, and on its marketing and product development support. Grünenthal insisted that its third party distributors follow its direction, direction these companies accepted and actions they took in hopes of securing the right to distribute thalidomide and the hope of reaping profits from that distribution.

318. Grünenthal exercised this direction and control in a number of ways, including through an agreement that it required licensees (like Merrell and Distllers) and other companies obtaining thalidomide for testing purposes (like SKF) execute. That agreement provided for mandatory disclosure of drug information between the parties, but upon information and belief, it precluded the parties from releasing scientific information detrimental to Grünenthal's interests. Grünenthal also exercised significant influence over the marketing of thalidomide products in its licensee countries by preparing marketing materials, instructing the companies as to the promotional messages to employ, and by providing expert witnesses to help develop marketing and promotional messages, and to help in the presentation of scientific data.

319. As stated above, each Defendant committed independently tortious acts by affirmatively misrepresenting that thalidomide was safe, particularly for use by pregnant women, and that it had been adequately tested when they knew this was false. Each Defendant committed independently tortious acts by hiding and concealing what they knew about thalidomide's ability to cause harm. They all hid and misrepresented the extent to which thalidomide had been tested, all concealing that it had not been tested on pregnant women.

They all hid their actual knowledge that thalidomide could cause birth defects in babies born to women taking the drug during pregnancy. Upon information and belief, SKF and Grünenthal (at least) hid the knowledge that thalidomide could cause birth defects in the offspring of pregnant animals that ingested thalidomide during pregnancy. They all hid and misrepresented what they knew or should have known about the fact that thalidomide had antithyroid effects, and that it caused nerve damage. Each of these known side effects should have raised the concern that thalidomide could cause birth defects, mandating disclosure of these side effects. None of them warned of the lack of testing or the health risks and side effects, and all concealed them, intentionally tortious acts constituting a breach of the duty of care to Plaintiffs.

320. Not only were all of these acts tortious, but they were all taken jointly by Defendants in pursuit of the common goal of maximizing profits while minimizing exposure to liability for the harm caused by their tortious conduct. The joint conduct was instigated by Grünenthal as developer and licensor of thalidomide. It was enforced through the licensing and testing agreements that each Defendant executed, and by Grünenthal's control and dominance over the rights to distribute thalidomide; the conduct was agreed upon, accepted and acted upon by all Defendants.

321. The plan was furthered when Grünenthal prepared, and its third parties agreed to use and disseminate, marketing, promotional and warning information known to be false and misleading because it concealed and downplayed known risks of harm. The plan was furthered when the Defendants engaged in aggressive marketing campaigns to promote thalidomide as adequately tested, "completely safe," "atoxic," and safe for ingestion by pregnant women. The

plan was furthered when all Defendants concealed the fact that no reproductive animal tests or controlled clinical trials investigating reproductive hazards had been conducted. The plan was furthered when Merrell sales men told its "clinical investigators"–Plaintiffs' physicians–that they need not make reports or keep records, and that they should distribute the drug on a sample basis. The plan was furthered when Defendants or their agents marketed and distributed thalidomide in unmarked packaging devoid of safety or identifying labels, packages containing thalidomide produced in such a variety of shapes and colors that it was difficult for patients to identify the drug they took. The plan was also furthered when Defendants failed to notify patients that they were participating in a human experiment, and to obtain their informed consent.

322. Defendants knew and intended that when they fraudulently misrepresented that thalidomide had been adequately tested, and that it was safe for pregnant women to ingest–representations made with the intent that Plaintiffs' and their physicians would rely on them so that Defendants could maximize profits and insulate themselves from liability–they would cause death and serious bodily injury. Because the birth defect risk created when a pregnant woman ingested thalidomide was so high, there was no question that concealing and misrepresenting that danger would cause serious injury. Therefore, Defendants' conspiracy to commit fraud and misrepresentation by concealing and misrepresenting the known and knowable hazards of thalidomide was malicious.

323. As a result of this conspiracy, fraudulent misrepresentations were made, directly or indirectly, to Plaintiffs' physicians and their mothers, who were unwitting participants in a massive human experiment for which no notice was given and no consent obtained. Plaintiffs'

physicians relied on the fraudulent misrepresentations and concealments in making prescribing decisions, and Plaintiffs' mothers relied on those misrepresentations and concealments by ingesting thalidomide drug products.

324. As a direct and proximate result of Defendants' conspiracy to commit fraud and misrepresentation and of their willful, wanton, and reckless conduct, Plaintiff suffered grievous, foreseeable, and permanent bodily injuries and consequent economic and other losses when Plaintiff's mother ingested thalidomide drug products which had been developed, formulated, designed, manufactured, sold, distributed, supplied, marketed and/or promoted, either directly or indirectly, by Defendants.

WHEREFORE, Plaintiff prays for judgment against Defendants in an amount which will compensate the Plaintiff for Plaintiff's injuries.

ALTER EGO
(GRÜNENTHAL DEFENDANTS)

325. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

326. Defendant Grünenthal USA, was established in 2001. It is a sham corporation created to permit Defendant Grünenthal GmbH to operate in the United States without a formal physical or corporate presence here. Upon information and belief, Grünenthal GmbH uses this U.S.-based entity as a vehicle through which to conduct its international pharmaceutical operations without, it hopes, exposing its own corporate assets to any accountability in this country.

327. In the years since the company stopped selling thalidomide, Grünenthal GmbH has continuously and systematically availed itself of U.S. markets, and of the markets of this state with respect to its sale and marketing of other drug products in this state to the present day. It has continued to manufacture drug products, including but not limited to tramadol, tapentadol/oxymorphone, and axomadol, and to systematically and continuously ship those products to the United States and into commercial markets in the United States and this state, acting through joint ventures and licensing agreements. One of Grünenthal's partnership arrangements was specifically entered into so that Grünenthal could "take part in events on the US market on short notice." Grünenthal GmbH's studies are relied upon by FDA in its consideration of New Drug Applications submitted for these drugs. Grünenthal GmbH obtains and holds U.S. patents for drug products; in 2009, almost half the patents awarded to the company were U.S. patents. Grünenthal GmbH has continuously received significant and financial benefits from these activities, revenues based on annual total net sales of such drugs.

328. Defendant Grünenthal GmbH created Grünenthal USA in 2001 so that it could oversee pharmaceutical drug clinical trials that Grünenthal GmbH conducts in furtherance of its U.S. pharmaceutical business activities without establishing a U.S. physical presence that might expose its corporate assets. Upon information and belief, Grünenthal USA is the alter ego of corporate parent, Grünenthal GmbH, as a result of some or all of the following particulars:

1) Since its creation in 1946, Grünenthal GmbH has operated as a closely-held family corporation, with the controlling interest in the company owned the Wirtz

family. According to court documents submitted by Grünenthal USA, Mr. Sebastian Wirtz has been a principal of Grünenthal USA, Inc.

2) Until recently, references to Grünenthal USA identified Sebastian Wirtz as the principal and chief executive of Grünenthal USA, while the *Financial Times* identified him as an executive board member as recently as 2007.

3) Upon information and belief, Grünenthal USA is a mere extension of its parent, Grünenthal GmbH, and would not be financially stable or viable on its own. It neither markets nor sells any products. Instead, the company and its staff of less than 20 does no more than provide operational, "branch office," support for the clinical trials Grünenthal GmbH and its U.S. licensing partners conduct. This is an internal oversight function, one for which there is no public demand or market. Upon information and belief, Grünenthal USA performs a service entirely and exclusively for its corporate parent, under the direction of its worldwide products and research operations. As such, upon information and belief, Grünenthal USA pays no dividends and would be insolvent in the absence of financing provided by Grünenthal GmbH, financing accounted for as payments for clinical trial management services.

4) Those worldwide products and research operations, operations based at Grünenthal GmbH's headquarters in Aachen, Germany, are managed and directed

by a member of Grünenthal GmbH's three-member executive board, Professor Eric-Paul Páques. Páques has management responsibility for Grünenthal GmbH's worldwide products portfolio, including specifically product research and development, and worldwide partnerships and alliances. Consistent with his responsibility to manage research and development for Grünenthal GmbH's worldwide portfolio of drug products, Páques is, upon information and belief, primarily responsible for major decisions concerning the company's clinical trials. Because Grünenthal USA's sole function is to provide oversight and support for those trials in the U.S., Páques has direct control over its operations. He has been President of Grünenthal USA since its incorporation in 2001. Upon information and belief, Grünenthal GmbH controls the operations of Grünenthal USA through the direction of Professor Páques.

5) Upon information and belief, Grünenthal USA holds various U.S. trademarks for products including but not limited to Abiantem. Because Grünenthal USA markets no products or services, it cannot be holding trademarks for its own benefit, but must hold them for the benefit of its corporate parent, Grünenthal GmbH.

6) Grünenthal USA has no independent corporate identity or purpose. While other Grünenthal GmbH subsidiaries have their own website, Grünenthal USA does not. Customers searching the Internet for information about Grünenthal USA are directed by search engines to Grünenthal GmbH's website. Apart for providing

an email address, virtually no mention is made of Grünenthal USA on Grünenthal GmbH's website, clearly implying that there is no anticipated demand or market for the services that Grünenthal USA provides. Instead, its sole purpose is to provide U.S.-based eyes and ears for its corporate parent, Grünenthal GmbH under the direction, control and dominance of that parent.

329. Grünenthal USA performs no services that are sold to entities other than the corporate parent, Grünenthal GmbH, and sells no product in the marketplace. It has no financial viability as an independent entity, and it has no purpose other than to facilitate the aims and goals of its corporate parent with respect to U.S. clinical trials. Grünenthal GmbH ensures that Grünenthal USA acts in a manner that is consistent with the goals of its parent, and that furthers its goals through the Presidency of Professor Eric-Paul Páques. There is a complete unity of interest between Grünenthal GmbH and Grünenthal USA.

330. Holding to the corporate fiction that these two companies are separate and independent entities is unjust. It allows Grünenthal GmbH to market and distribute its pharmaceutical products in this country *and* to maintain some corporate presence here while insulating its corporate assets from accountability for its actions.

WHEREFORE, Plaintiff prays for judgment against Grünenthal GmbH and Grünenthal USA as the alter ego of Grünenthal GmbH in an amount which will compensate the Plaintiff for Plaintiff's injuries.

PUNITIVE DAMAGES
(ALL DEFENDANTS)

331. Plaintiffs repeat, reiterate, and reallege each and every allegation set forth above with the same force and effect as if copied herein.

332. By 1956, all Defendants knew that the administration of drugs to pregnant women posed a hazard to the fetus if those medications could penetrate the placenta. As a consequence, pharmaceutical companies were well aware that it was important to conduct animal reproductive tests and controlled clinical trials on any drug that was intentionally marketed to pregnant women, or drugs that would be foreseeably used by pregnant women. Both SKF and Merrell (as well as other pharmaceutical companies) had made it a practice to conduct such tests before distributing other drugs, including triparanol/MER 29 (Merrell) and Thorazine (SKF). Pharmaceutical companies also recognized that limited and controlled clinical trials involving pregnant women–trials that provided notice to a participant and proceeded only after that participant gave their informed consent–were another important prerequisite to the marketing of a drug that would be used by pregnant women.

333. It was also known or knowable to all Defendants by 1955 that the molecular weight of thalidomide was 258 and that substances with a molecular weight under 1000 could cross the placental wall, reaching the fetus.

334. Despite these known risks, none of these Defendants has admitted to conducting a single animal reproductive test or controlled clinical trial before distributing thalidomide drug

products to pregnant women. Worse, each Defendant represented to physicians and the public that thalidomide had been adequately tested.

335. Each Defendant knew that thalidomide caused neurological damage prior to their distribution of the drug. All Defendants also knew or should have known that at least one of the metabolites of thalidomide mimicked the B vitamin, folic acid, giving rise to the potential to interfere with the metabolism of those B vitamins, creating a known birth defect risk. All Defendants also knew or should have known that the chemical composition of thalidomide was similar to that of a known teratogenic agent, aminopterin, and that due to this chemical similarity, thalidomide had the potential to cause birth defects. Each Defendant knew no later than 1955 that thalidomide depressed the action of the thyroid gland, and that hypothyroidism during pregnancy created a birth defect risk. Although each Defendant was aware of these facts, and the risks they created, none warned about the risk and all concealed it.

336. By 1959, Grünenthal and Merrell at least, knew that thalidomide was highly toxic to laboratory animals when delivered in syrup form, but they both concealed this information and continued to misrepresent to the present day that they had been unable to determine a toxic dose, or LD-50, for the drug. The purported inability to establish an LD-50 for thalidomide was the key foundation for the companies' contentions that thalidomide was safe, harmless and atoxic.

337. By 1956, Defendant Grünenthal gained actual knowledge that thalidomide could cause birth defects in humans because the wives of its employees were giving birth to malformed babies after taking thalidomide during pregnancy. Upon information and belief, Grünenthal knew of this risk, but concealed it and failed to warn about it. It also refused to conduct further

testing to investigate the birth defect hazard, and discouraged its third party distributors from conducting such testing.

338. By 1958, Defendants Grünenthal and SKF gained actual knowledge that thalidomide could cause birth defects in humans because at least one, if not two phocomelic babies was born during the SKF clinical trial. Merrell should have had actual knowledge of this risk no later than 1960, nine months after its clinical trials of pregnant women commenced. Though they knew of this risk, they all concealed it and failed to warn about it. SKF President Walter Munns lied to Congress about this finding.

339. Grünenthal and Merrell also refused to conduct further testing to investigate the birth defect hazard; upon information and belief, Grünenthal discouraged its third party distributors from conducting such testing.

340. All Defendants had an actual subjective knowledge of the birth defect risk created when pregnant women ingested thalidomide, as outlined above. Instead of conducting appropriate testing to either rule out or define that risk, Defendants concealed it and intentionally distributed thalidomide to pregnant women. Grünenthal and Merrell, at a minimum, intentionally targeted pregnant women in their marketing campaigns and represented that the drug was safe for the treatment of the nausea of early pregnancy.

341. All Defendants concealed the fact that thalidomide had not been tested on any pregnant animals or in any controlled clinical trials, before it was distributed to pregnant women, instead maintaining that the drug had been adequately tested before use in humans commenced.

342. All Defendants concealed the known and knowable hazards posed by thalidomide and instead misrepresented that the drug was safe.

343. This conduct is malicious, willful, wanton and reckless. It is also conduct taken in conscious disregard for the safety of Plaintiffs.

WHEREFORE, Plaintiffs seek punitive damages from all Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

344. For judgment sufficient to compensate Plaintiffs for the damages suffered, including but not limited to:

1) past, present, and future economic damages in connection with the injuries sustained by the Plaintiffs as a result of their mother's ingestion of thalidomide during pregnancy;

2) compensatory damages, according to proof, including damages for physical injuries, pain and suffering, mental anguish, emotional distress, embarrassment, shame, anguish, anxiety, and loss of enjoyment of life;

3) general damages in the amount to be determined for the wrongful conduct of the Defendants;

4) reasonable costs, including attorneys' fees permitted by law;

5) prejudgment and postjudgment interest as provided by law;

6) punitive damages; and

7) such further relief as this court deems necessary, just and proper.

345. Plaintiffs also seek the recovery of past, present and future special damages, including medication, medical expenses, rehabilitation expenses, assisted living and nursing care.

JURY DEMAND

Further Plaintiffs hereby request a trial by jury on all claims set forth herein.

Dated August 26, 2011

Respectfully submitted,

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VERIFICATION

I, Richard D. Meadow, hereby state that I am counsel for Plaintiffs Glenda Johnson and Steven Lucier in this action and verify that the statements made in the foregoing Plaintiffs' Complaint are true and correct to the best of my knowledge, information and belief I understand that this statement and verification is made subject to the penalties of 18 P.A.C.S. Section 4904 relating to unsworn falsification to authorities, which provide that if I knowingly make false statements, I may be subject to criminal penalties.

Date: August 26, 2011

Richard D Meadow

RICHARD D. MEADOW, ESQ.